UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK	X	USDC SDNY DOCUMENT ELECTRONICALLY FILED DOC #:_ DATE FILED: 02/11/2022
In re: Elysium Health-ChromaDex Litigation	: : : :	17-ev-7394 (LJL)
	:	OPINION AND ORDER
	X	

LEWIS J. LIMAN, United States District Judge:

Plaintiff ChromaDex, Inc. ("ChromaDex") and Defendant Elysium Health ("Elysium") cross-move for summary judgment pursuant to Federal Rule of Civil Procedure 56. Elysium moves for summary judgment on ChromaDex's claims, and both parties move for summary judgment on Elysium's counterclaims.

For the following reasons, the motions for summary judgment are each granted in part and denied in part.

#### BACKGROUND

Familiarity with the Court's prior opinions denying in part ChromaDex's motion to dismiss and granting in part and denying in part Elysium's motion to dismiss ChromaDex's counterclaims, Dkt. No. 44, and granting ChromaDex's motion for summary judgment as to Elysium's claims regarding ChromaDex's citizen petition under the *Noerr-Pennington* doctrine, Dkt. No. 63, is assumed.

The following facts are undisputed for the purposes of summary judgment except where otherwise indicated.

### I. The Parties

This case arises from a dispute over the sales of, and credit for, nutritional products claimed to improve cellular health and cellular aging.

ChromaDex, which was founded in 1999, is a publicly traded nutraceutical company which, until recently, manufactured and sold chemical compounds only as a wholesaler to companies which incorporated ChromaDex's ingredients into their products for retail consumption. Dkt. No. 230-32 ("Joint 56.1") ¶¶ 1–2. NIAGEN® ("Niagen") is one of ChromaDex's products. *Id.* ¶ 3. The active ingredient in Niagen is ChromaDex's synthetically-produced isolated nicotinamide riboside ("NR"). *Id.* ¶ 4. NR is a naturally occurring form of Vitamin B<sub>3</sub> that increases nicotinamide adenine dinucleotide or NAD+, an essential coenzyme required for life and cellular functions. Joint 56.1 ¶¶ 7–8, 10; *see also* Dkt. No. 210 at 3; Dkt. No. 222 at 4. NAD+ is linked to cellular health and cellular aging. In 2000, Dr. Leonard Guarente—who is a co-founder and the Chief Scientific Advisor of Elysium—co-authored a paper on sirtuins, a family of proteins that regulate cellular health and cellular homeostasis. Guarente describes the paper as showing that Sir2, a sirtuin in yeast, controls aging in yeast cells and that NAD+ is necessary for Sir2 activity. Dkt. No. 221 ("Elysium's 56.1") ¶ 9. By increasing NAD+, NR is believed to improve cellular health and slow cellular aging.

Scientists have known about NAD+ since it was first discovered in 1906. *Id.* ¶ 10. NR has been in the scientific literature since the 1940s "as a growth factor for haemophilus influenzae." Joint 56.1 ¶ 7; *see also* Elysium's 56.1 ¶ 12; Dkt. No. 210 at 3; Dkt. No. 222 at 4. In 2007, ChromaDex's Chief Scientific Advisor, Dr. Charles Brenner, co-authored a study showing that NR increases NAD+ and Sir2 function. Dkt. No. 217, Ex. B. Six years later, ChromaDex launched Niagen, its synthetic isolated form of NR. When ChromaDex launched Niagen, it operated as a wholesaler and supplied the ingredient to other companies. Joint 56.1 ¶

24. It did the same with other ingredients it manufactured, including pTeroPure, its synthetic pterostilbene ("PT").

ChromaDex's co-founder and executive chairman is Frank Jaksch. Dkt. No. 257, Ex. 6 at 12. He was ChromaDex's CEO until approximately 2018; ChromaDex's current CEO is Rob Freed. *Id.* From December 2013 to August 2016, Dr. Ryan Dellinger was employed by ChromaDex as Director of Scientific Affairs. Dkt. No. 229 ¶ 7.

Elysium was until recently one of ChromaDex's customers. It is a dietary supplement company that sells directly to customers. Elysium was founded in 2013; its founders included Guarente, Dan Alminana, and Eric Marcotulli. The idea behind Elysium was to start a dietary supplement company grounded in science, serving consumers in between the nutraceutical space and the pharmaceutical space. Elysium's 56.1 ¶¶ 48–49.

Elysium's primary product is a dietary supplement called Basis, a direct-to-consumer product which combines NR with PT. *Id.* ¶¶ 22–23. Elysium launched Basis in February 2015. Until approximately August 2016, Elysium obtained its NR and PT from ChromaDex. Elysium entered into a supply agreement with ChromaDex on February 3, 2014, in which ChromaDex agreed to supply Elysium with Niagen. Joint 56.1 ¶ 20. ChromaDex supplied Elysium with NR in the form of Niagen from February 2015 until August 2016. *Id.* ¶ 24. Elysium also entered into a supply agreement with ChromaDex on June 26, 2014, in which ChromaDex agreed to supply Elysium with PT. *Id.* ¶ 21. After Elysium entered into the supply agreements with ChromaDex but before it launched Basis, in about September 2016, Dellinger, who previously had been employed as ChromaDex's Director of Scientific Affairs, left ChromaDex and joined Elysium as Director of Scientific Affairs. In approximately April 2020, Dellinger became Elysium's Vice President of Scientific Affairs. Dkt. No. 229 ¶ 8. Elysium's Chief Product

Officer is Mark Morris. Dkt. No. 227 ¶ 1. Morris was also previously employed by ChromaDex, from June 2007 to August 2009 and from January 2011 to July 2016. *Id.* ¶ 2. He joined Elysium in around July 2017 as Vice President of Research and Development, and in 2020 became Elysium's Chief Product Officer. *Id.* ¶ 3.

In approximately November 2016, ChromaDex sent Elysium a notice of non-renewal and terminated its agreements to supply Elysium with NR and PT. Elysium's 56.1 ¶¶ 74, 78. In March 2017, ChromaDex began selling a direct-to-consumer dietary supplement called TRU NIAGEN® ("Tru Niagen"), in which the only active ingredient is 300 mg of Niagen. Joint 56.1 ¶¶ 5–6.

After ChromaDex ceased to supply Elysium with NR and PT, in late 2016, Elysium began to develop its own method for manufacturing NR. Elysium's 56.1 ¶ 80. Elysium continued to produce and sell Basis and had other companies manufacture NR on its behalf and supply it with PT. Joint 56.1 ¶¶ 27–34.

# II. FDA Regulation of Niagen, Tru Niagen, and Basis

The FDA regulates dietary supplements, and the ingredients they use, through various regulatory mechanisms. First, under the 1958 Food Additives Amendment to the federal Food, Drugs, and Cosmetic Act, any "food additive"—meaning a substance intentionally added to food—must undergo premarket approval by the FDA, subject to certain exemptions. Dkt. No. 209-3 ("Weisman Report") at 1 (citing 21 U.S.C. § 321(s)). One such exemption is for food ingredients that are found by qualified experts to be "generally recognized as safe" ("GRAS") for their intended use. To obtain GRAS status, companies must submit a dossier of historical and scientific evidence of safety to an independent panel of experts, who then find the substance to be GRAS. *Id.* at 5 (citing 81 Fed. Reg. 54,960 (Aug. 17, 2016) (codified at 21 C.F.R. pts. 20, 25, 170, 184, 186 & 570)). Once the GRAS expert panel issues a finding, that finding can either be

voluntarily submitted to the FDA, or the company can choose not to submit the GRAS finding to the FDA. In the former case, the FDA "evaluates whether the submitted notice is sufficient for a GRAS determination or whether the information in the notice (or otherwise available) raises potential questions on whether the substance is indeed GRAS." *Id.* at 7. The FDA's review is managed by a consumer safety officer who determines exactly what kinds of expertise is needed to review a particular GRAS submission. Dkt. No. 230-31 ("ChromaDex's 56.1") ¶ 7; Dkt. No. 249 ¶ 7. The FDA's review includes a consumer safety officer, a chemist, a toxicologist, sometimes a microbiologist, sometimes a food scientist, and sometimes a nutritionist. ChromaDex's 56.1 ¶ 8; Dkt. No. 249 ¶ 8. The FDA responds either by issuing a "no objection" letter or by concluding that the notice is insufficient to provide evidence of a GRAS conclusion. Alternatively, if the finding is not submitted to the FDA, the GRAS status "should be of the same scientific rigor as a GRAS notification submitted to the FDA." Weisman Report at 7. In that case, "the basis for the independent GRAS conclusion should be made publicly available by placing a document analogous to the GRAS notice and/or a report of any GRAS panel on the sponsor's website." Id.

On December 21, 2015, Niagen was generally recognized as safe by an independent panel of expert toxicologists for the intended use of Niagen "as an ingredient in vitamin waters, protein shakes, nutrition bars, gum and chews." ChromaDex's 56.1 ¶ 4 (citing Dkt. No. 230, Ex. 10); Dkt. No. 230, Ex. 10 at 1. On March 8, 2016, ChromaDex submitted its GRAS dossier and the expert panel statement to the FDA and received the response: "Based on the information provided by ChromaDex, as well as other information available to the FDA, the agency has no questions at this time regarding ChromaDex's conclusion that NR is GRAS under the intended

conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of NR." ChromaDex's 56.1 ¶ 5; Dkt. No. 249 ¶ 5.

Elysium prepared a "GRAS Notification of Nicotinamide Riboside Chloride," dated October 27, 2021, and a "Comprehensive GRAS Assessment of Pterostilbene," dated February 2, 2018. Joint 56.1 ¶¶ 39–40. Elysium did not notify the FDA of its GRAS self-affirmation for NR or PT. *Id.* ¶ 41. The panel reviewing Elysium's GRAS assessment for NR concluded that "Elysium's NR, when produced in accordance with FDA Good Manufacturing Practices requirements and when meeting those specifications presented by Elysium in Table 2, is Generally Recognized as Safe when consumed at the proposed levels [250mg/day] in conventional food and dietary supplements." Dkt. No. 227, Ex. C at 39. Elysium's GRAS assessment for PT was not reviewed by an independent panel. Dkt. No. 257, Ex. 18 at 125.

The FDA also regulates new dietary ingredients ("NDIs"). An NDI is "a dietary ingredient that was not marketed in the United States before October 15, 1994." 21 U.S.C. § 350b(d). Under the Federal Food, Drug and Cosmetic Act, "a dietary supplement which contains a new dietary ingredient shall be deemed adulterated" unless it "contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered" or the manufacturer or distributor of the dietary ingredient or dietary supplement submits a notification (an "NDI notification" or "NDIN") to the FDA with information regarding the history of use or other evidence of safety of the dietary ingredient based on which "the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe" at least seventy-five days before introducing the product to market. *Id.* § 350b(a).

On or about August 20, 2015, ChromaDex submitted an NDIN to the FDA for Niagen; it submitted a second NDIN for Niagen on December 27, 2017. Joint 56 ¶¶ 17–18. Elysium has never submitted an NDIN to the FDA for Basis, NR, or PT. *Id.* ¶ 38. Elysium asserts that it initially intended to submit an NDIN for Basis, but confirming the GRAS status of Elysium's NR and PT was Elysium's business priority because GRAS has a broader application than NDIN. Elysium's 56.1 ¶ 87 (citing Dkt. No. 227 ¶ 16).

Under an alternate regulatory pathway for new drugs, a sponsor may submit an investigational new drug application (an "IND") to the FDA. 21 C.F.R. § 312.20(a). INDs are reviewed by the FDA and include a safety determination component. Elysium's 56.1 ¶ 93; Dkt. No. 257, Ex. 34 at 32. The regulatory processes for an NDI and an IND are different, but they are similar in terms of the scientific rigor around safety. Elysium's 56.1 ¶ 96; Dkt. No. 257, Ex. 34 at 33. In 2019, the FDA accepted Elysium's IND application to evaluate the efficacy of Basis for the prevention of acute kidney injury in surgical cardiac patients. Elysium's 56.1 ¶ 92.

#### **III.** The Relevant Studies

The parties have each conducted and rely upon—both in their marketing and before this Court—various studies related to the safety and efficacy of NR and their products.

The first published human clinical study of synthetic isolated NR was published on October 10, 2016 in the journal *Nature Communications*. It was titled "Nicotinamide riboside is uniquely and orally bioavailable in mice and humans" (the "Trammell Study"). Joint 56.1 ¶ 9. The Trammell Study used ChromaDex's Niagen and reported that a single dose of NR increased NAD+ level in blood over a twenty-four-hour period. *Id.* ¶¶ 10, 16. The co-authors of the Trammell Study included, among others, Jaksch, Dellinger, and Brenner, all of whom were then working at or during the period of the study had worked at ChromaDex. In the study's clinical trial, "[t]welve healthy, non-pregnant subjects (six male and six female) were recruited and

randomized to one of three treatment sequences." Dkt. No. 229, Ex. A at 12. After fasting overnight, the subjects received a single morning dose of either 100 mg, 300 mg, or 1,000 mg of NR. *Id.* This was done on three test days, separated by seven-day periods with no supplement given. *Id.* The study reported dose-dependent increases in NAD+ levels following administration of 100 mg, 300 mg, and 1000 mg single doses of NR in adults. Joint 56.1 ¶ 11. There were no serious adverse effects in participants in the Trammell Study. *Id.* ¶ 12.

In 2017, Elysium published a study titled "Repeat Dose NRPT (nicotinamide riboside and pterostilbene) increases NAD+ levels in humans safely and sustainably: a randomized, double-blind, placebo-controlled study" (the "Dellinger Study"). *Id.* ¶ 42. The Dellinger Study examined Basis; the NR and PT ingredients used in the Dellinger Study were ChromaDex-supplied Niagen and pTeroPure. *Id.* ¶ 43. The study contained three groups: (1) approximately forty participants received a placebo for eight weeks; (2) approximately forty participants received a single dose of Basis for eight weeks (the "NRPT 1X group"); and (3) approximately forty participants received a double dose of Basis for eight weeks (the "NRPT 2X group"). Dkt. No. 229 ¶ 12, Ex. C. The study showed a dose-dependent increase in NAD+ levels sustained over the course of the trial. *Id.* 

A six-week randomized, double blind, controlled cross-over clinical study of thirty middle-aged and older healthy volunteers was published in *Nature Communications* in 2018, entitled "Chronic nicotinamide riboside supplementation is well-tolerated and elevates NAD(+) in healthy middle-aged and older adults" (the "Martens Study"). Joint 56.1 ¶ 15. The Martens Study tested ChromaDex's Niagen. *Id.* ¶ 16. In this study, thirty healthy male and female participants between the ages of fifty-five and seventy-nine were randomized into one of two groups: Group A received placebo capsules during the first six weeks of the study and then

crossed over to receive NR capsules for the remaining six weeks at a 1000 mg per day dosage, and Group B did the opposite, receiving NR capsules first and then placebo capsules. Dkt. No. 230, Ex. 14 at 3–4. The study found that "NR was well tolerated at the dose tested, and no serious adverse effects occurred." *Id.* at 4.

In an eight-week study published in 2019, researchers evaluated the kinetics and dose-dependence of synthetic isolated NR oral availability and safety in overweight but otherwise healthy men and women (the "Conze Study"). Joint 56.1 ¶ 14. The Conze Study also tested ChromaDex's Niagen. *Id.* ¶ 16. In the ninety-day study, on which Charles Brenner was a co-author, 140 healthy male and female participants between ages forty and sixty were randomly assigned to different groups, and, during the eight-week interventional period of the study, received either 100 mg, 300 mg, or 1000 mg of NR per day, or a placebo. Dkt. No. 230, Ex. 15, at 2–3. The study also contained a two-week run-in period. *Id.* The participants were instructed to avoid foods containing high amounts of tryptophan and forms of vitamin B<sub>3</sub> during the run-in and NR supplementation periods. *Id.* at 2. The study concluded that NR produces dose-dependent increase in blood and urinary NAD+ metabolites, and that oral Niagen is safe and well-tolerated up to 1000 mg per day for eight weeks. *Id.* at 6, 8.

Elysium sponsored a clinical study published on August 3, 2020, entitled "Nicotinamide riboside with pterostilbene (NRPT) increases NAD+ in patients with acute kidney injury (AKI): a randomized, double-blind, placebo-controlled, stepwise safety study of escalating doses of NRPT in patients with AKI" (the "Simic Study"). Elysium's 56.1 ¶ 88. Elysium asserts that the Simic Study used Elysium's NR. *Id.* ¶ 89. The study was made up of four steps, in which NRPT was given to five subjects and a placebo was given to one subject twice a day for two days; the dosage was increased in each step. Dkt. No. 229, Ex. E at 1. The study showed that, "compared

to the baseline timepoint, NRPT at all doses increased whole blood NAD+ levels at 48 h, but only the increase with NRPT Step 2 (dose 500 mg/100 mg) reached statistical significance." *Id.* at 4. It further found that "NRPT was safe at all doses with only minor side effects reported that resolved without intervention." *Id.* at 7.

### IV. Other Litigation Between ChromaDex and Elysium

Since Elysium's launch of Basis and ChromaDex's launch of Tru Niagen, the two companies have sued each other in several different federal courts.

In 2018, ChromaDex sued Elysium for patent infringement in the Delaware District Court. Joint 56.1 ¶ 51. ChromaDex's complaint alleged that Basis infringes various patents ChromaDex held related to the formulation of isolated NR for oral consumption. *See ChromaDex, Inc. et al v. Elysium Health, Inc.*, Case No. 1:18-cv-1434-CFC-JLH, ECF No. 1 ¶¶ 23–28. On September 21, 2021, Judge Connolly granted Elysium's motion for summary judgment in that action, holding that the allegedly-infringed patent claims "are invalid under 35 U.S.C. § 101 for claiming patent-ineligible subject matter." *See ChromaDex, Inc. v. Elysium Health, Inc.*, --- F. Supp. 3d ---, 2021 WL 4286527, at \*5 (D. Del. Sept. 21, 2021).

The two companies are also adversaries in a lawsuit filed in the Central District of California, in which ChromaDex alleges claims for breach of contract, breach of fiduciary duty, and misappropriation of trade secrets and Elysium alleges counterclaims for breach of contract, fraudulent inducement, patent misuse, and unjust enrichment. *See* Dkt. No. 171 at 1. A jury trial was held in that action from September 21, 2021 to September 27, 2021; the jury returned a verdict for ChromaDex on its breach of contract claim, for Elysium on ChromaDex's misappropriation of trade secrets claims, for Elysium on ChromaDex's aiding and abetting breach of fiduciary duty claim, for Elysium on its breach of contract counterclaim, and for Elysium on its fraudulent inducement counterclaim, and found that ChromaDex acted with

malice, oppression, or fraud, and returned an award for punitive damages accordingly. *See* Case No. 8:16-cv-02277-CJCC-DFM, Dkt. Nos. 554–573.

#### PROCEDURAL HISTORY

This case has had a long and tortuous procedural history, which is set out in detail in the Court's Opinion and Order at Dkt. No. 171. For purposes of this motion for summary judgment, the relevant procedural history is as follows.

ChromaDex first filed its complaint in this action on September 27, 2017. Dkt. No. 1. ChromaDex's operative complaint is the second amended complaint, Dkt. No. 139 ("SAC" or "Complaint"), which was filed on February 27, 2020. The Complaint alleges claims for false advertising under the Lanham Act, 15 U.S.C. § 1125(a), federal unfair competition under the Lanham Act, and deceptive practices under New York General Business Law § 349.

Elysium's operative counterclaim is the fourth amended counterclaim, Dkt. No. 192 ("Counterclaim"), which was filed on April 21, 2021. The Counterclaim alleges claims under the same statutes as those alleged in the Complaint—false advertising under the Lanham Act, federal unfair competition under the Lanham Act, and deceptive practices under New York General Business Law § 349.

On June 4, 2021, Elysium filed its motion for summary judgment on ChromaDex's claims against it, and for partial summary judgment on its counterclaims, Dkt. No. 203, and ChromaDex filed its motion for summary judgment on Elysium's counterclaims, Dkt. No. 204. On June 25, 2021, ChromaDex filed its opposition to Elysium's motion, and Elysium filed its opposition to ChromaDex's motion. Dkt. Nos. 242, 250. The parties filed replies in further support of their respective motions on July 9, 2021 and July 10, 2021. Dkt. Nos. 262, 273.

#### LEGAL STANDARD

# I. Summary Judgment

Under Federal Rule of Civil Procedure 56, a court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "When the burden of proof at trial would fall on the nonmoving party, it ordinarily is sufficient for the movant to point to a lack of evidence to go to the trier of fact on an essential element of the non-movant's claim." Jaramillo v. Weyerhaeuser Co., 536 F.3d 140, 145 (2d Cir. 2008). If the movant meets its burden, "the nonmoving party must come forward with admissible evidence sufficient to raise a genuine issue of fact for trial in order to avoid summary judgment." Id. "An issue of fact is 'material' for these purposes if it 'might affect the outcome of the suit under the governing law," while "[a]n issue of fact is 'genuine' if 'the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Konikoff v. Prudential Ins. Co. of Am., 234 F.3d 92, 97 (2d Cir. 2000) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). In determining whether there are any genuine issues of material fact, the Court must view all facts "in the light most favorable to the non-moving party," Holtz v. Rockefeller & Co., Inc., 258 F.3d 62, 69 (2d Cir. 2001), and the movant bears the burden of demonstrating that "no genuine issue of material fact exists," Marvel Characters, Inc. v. Simon, 310 F.3d 280, 286 (2d Cir. 2002) (citations omitted).

"[A] party may not rely on mere speculation or conjecture as to the true nature of the facts to overcome a motion for summary judgment." *Hicks v. Baines*, 593 F.3d 159, 166 (2d Cir. 2010) (quoting *Fletcher v. Atex, Inc.*, 68 F.3d 1451, 1456 (2d Cir. 1995)). Nor may the non-moving party "rely on conclusory allegations or unsubstantiated speculation." *F.D.I.C. v. Great Am. Ins. Co.*, 607 F.3d 288, 292 (2d Cir. 2010) (quoting *Scotto v. Almenas*, 143 F.3d 105,

114 (2d Cir. 1998)). Rather, to survive a summary judgment motion, the opposing party must establish a genuine issue of fact by "citing to particular parts of materials in the record." Fed. R. Civ. P. 56(c)(1)(A); see also Wright v. Goord, 554 F.3d 255, 266 (2d Cir. 2009). To defeat a motion for summary judgment, the non-moving party must demonstrate more than "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The non-moving party "cannot defeat the motion by relying on the allegations in [its] pleading, or on conclusory statements, or on mere assertions that affidavits supporting the motion are not credible." *Gottlieb v. Cnty. of Orange*, 84 F.3d 511, 518 (2d Cir. 1996) (internal citation omitted).

"[W]hen multiple parties cross-move for summary judgment, . . . 'each party's motion must be examined on its own merits and in each case all reasonable inferences must be drawn against the party whose motion is under consideration." *Century Sur. Co. v. Franchise Contractors, LLC*, 2016 WL 1030134, at \*3 (S.D.N.Y. Mar. 10, 2016) (quoting *Morales v. Quintel Ent., Inc.*, 249 F.3d 115, 121 (2d Cir. 2001)).

The Southern District's Local Civil Rule 56.1 sets forth specific requirements about how the facts relied upon by the moving party and disputed by the opposing party are to be presented. Any party moving for summary judgment must "annex[] to the notice of motion a separate, short and concise statement, in numbered paragraphs, of the material facts as to which the moving party contends there is no genuine issue to be tried." L.R. 56.1(a). Local Rule 56.1(b), in turn, requires the party opposing the motion to "include a correspondingly numbered paragraph responding to each numbered paragraph in the statement of the moving party, and if necessary, additional paragraphs containing a separate, short and concise statement of additional material facts as to which it is contended that there exists a genuine issue to be tried." L.R. 56.1(b). All

statements in a Local Rule 56.1 submission "must be followed by citation to evidence which would be admissible." L.R. 56.1(d). "Each numbered paragraph in the statement of material facts set forth in the statement required to be served by the moving party will be deemed to be admitted for purposes of the motion unless specifically controverted by a correspondingly numbered paragraph in the statement required to be served by the opposing party." L.R. 56.1(c).

# II. False Advertising Under the Lanham Act

Section 43(a) of the Lanham Act, codified at 15 U.S.C. § 1125(a), provides in relevant part that:

(1) Any person who, on or in connection with any goods or services, . . . uses in commerce . . . any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—

. . .

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a). A false advertising claim under 15 U.S.C. § 1125(a)(1)(B) thus applies only to "commercial advertising or promotion." *Id.*; *see also Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 57 (2d Cir. 2002).

"To prevail on a Lanham Act false advertising claim, a plaintiff must establish that the challenged message is (1) either literally or impliedly false, (2) material, (3) placed in interstate commerce, and (4) the cause of actual or likely injury to the plaintiff." *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH*, 843 F.3d 48, 65 (2d Cir. 2016) (citing *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 255–56 (2d Cir. 2014)).

### A. Falsity

Falsity can be established in two ways. First, "[t]o establish literal falsity, a plaintiff must show that the advertisement either makes an express statement that is false or a statement that is 'false by necessary implication,' meaning that the advertisement's 'words or images, considered in context, necessarily and unambiguously imply a false message." *Id.* (quoting *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007)). "A message can only be literally false if it is unambiguous." *Id.* 

Second, "[i]f a message is not literally false, a plaintiff may nonetheless demonstrate that it is impliedly false if the message leaves 'an impression on the listener or viewer that conflicts with reality." Id. (quoting Time Warner Cable, 497 F.3d at 153). "Where the statement at issue is not literally false,' a plaintiff alleging a Lanham Act violation 'must demonstrate, by extrinsic evidence, that the challenged content tends to mislead or confuse consumers, and must demonstrate that a statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement." Board-Tech Electronic Co., Ltd. v. Eaton Corp., 737 F. App'x 556, 560 (2d Cir. 2018) (summary order) (internal alterations omitted) (quoting Tiffany (NJ) Inc. v. eBay Inc., 600 F.3d 93, 112–13 (2d Cir. 2010)); see also Time Warner Cable, 497 F.3d at 153 ("[A] district court must rely on extrinsic evidence to support a finding of an implicitly false message." (internal alterations and citations omitted)); Board-Tech, 737 F. App'x at 560–61 (citing *Time Warner Cable* for the same proposition). As will be seen, the parties offer only limited extrinsic evidence with regard to implied falsity; as such, most of the challenged statements rise or fall on the question whether they are literally false.

### B. Materiality

"Falsity alone does not make a false advertising claim viable; 'under either theory, the plaintiff must also demonstrate that the false or misleading representation involved an inherent or material quality of the product." *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 63 (2d Cir. 2016) (quoting *Time Warner Cable*, 497 F.3d at 153 n.3). "Such a 'requirement is essentially one of materiality, a term explicitly used in other circuits." *Id.* (quoting *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 238 (2d Cir. 2001)). The Second Circuit "has defined materiality as 'likely to influence purchasing decisions,' a definition in harmony with other Circuits' use of the term." *Id.* (quoting *Nat'l Basketball Ass'n v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997)); *see also Church & Dwight*, 843 F.3d at 70 n.11 (noting that *Apotex* "recently settled the materiality standard in this Circuit, explaining that the standard is whether the deception is 'likely to influence purchasing decisions'" (quoting *Apotex*, 823 F.3d at 63)).

Thus, to establish a Lanham Act claim, the plaintiff must demonstrate that the statement at issue involved an inherent or material quality of the product and that the deception is likely to influence purchasing decisions.

# C. Injury

A Section 43(a) false advertising plaintiff must also establish "that 'the plaintiff . . . has been injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products." *Merck Eprova*, 760 F.3d at 255 (quoting *Cashmere & Camel Hair Mftrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 311 (1st Cir. 2002)). "A plaintiff must show that its injury was 'caused by or attributable to' the false advertisements, as opposed to a lawful factor, like a defendant's lower prices." *Dependable Sales & Serv., Inc. v. TrueCar, Inc.*, 311 F. Supp. 3d 653, 659 (S.D.N.Y. 2018) (quoting *Burndy Corp. v. Teledyne Indus., Inc.*, 748 F.2d 767, 773 (2d Cir. 1984)).

A presumption of injury arises where the false or misleading advertising makes reference "to a specific competing product," which "necessarily diminishes that product's value in the minds of the consumer," *McNeilab, Inc. v. American Home Prods Corp.*, 848 F.2d 34, 38 (1988), and where "even though [the challenged advertising] does not identify [the competitor] by name, consumers . . . undoubtedly understand [the] derogatory statement . . . as referring to [the competitor]," *Time Warner Cable*, 497 F.3d at 162. A presumption of injury also arises "where . . . a plaintiff has met its burden of proving deliberate deception in the context of a two-player market, . . . even if it is not a classic instance of comparative advertising where one company's advertisement mentions a competitor's product by name." *Merck Eprova*, 760 F.3d at 260–61.

"[A] plaintiff who establishes false advertising in violation of § 43(a) of the Lanham Act will be entitled only to such damages as were caused by the violation." *Burndy*, 748 F.2d at 771. "Although a court may engage in some degree of speculation in computing the *amount* of such damages, particularly when the inability to compute them is attributable to the defendant's wrongdoing, causation must first be established." *Id.* (internal citations omitted). "It is the plaintiff's burden to demonstrate that false advertisements resulted in lost sales." *Dependable Sales*, 311 F. Supp. 3d at 659. A plaintiff seeking injunctive relief, however, does not need to quantify actual damages. "The statute demands only proof providing a reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the false advertising." *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir. 1980). "The correct standard is whether it is likely that [the defendant's] advertising has caused or will cause a loss of [the plaintiff's] sales, not whether [plaintiff] has come forward with specific evidence that [the defendant's] ads actually resulted in some definite loss of sales." *Id.* As a general matter,

however—except in cases in which a presumption of injury and causation applies—"the likelihood of injury and causation will not be presumed, but must be demonstrated." *Id.*<sup>1</sup>

#### **DISCUSSION**

Elysium moves for summary judgment on ChromaDex's claims against it. ChromaDex, in turn, moves for summary judgment on Elysium's counterclaims against it, and Elysium moves for partial summary judgment in its favor on the counterclaims. The Court addresses both parties' motions as to the Lanham Act false advertising claims first, and then turns to the remaining claims.

# I. The Parties' Lanham Act False Advertising Claims

# A. Advertising or Promotion

Only one category of claims is challenged as not constituting advertising or promotion. Elysium's Counterclaim asserts a Lanham Act false advertising claim based on statements that appeared on a blog called Right of Assembly. ChromaDex moves for summary judgment on this counterclaim. It argues that it has no liability for these statements that appeared on a third-party blog, regardless whether they were false, material, or caused injury, because the statements are not covered by the Lanham Act at all because they do not constitute "advertising or promotion." It further argues that even if the statements are actionable under the Lanham Act, they were not made by ChromaDex. Both arguments are well-taken.

<sup>&</sup>lt;sup>1</sup> ChromaDex recites the *Johnson & Johnson* standard as if it applied to all claims at the summary judgment stage and not just those seeking injunctive relief. However, *Johnson & Johnson* itself clearly distinguishes between a claim for money damages and a claim for injunctive relief and holds that the standard applies only to plaintiffs seeking injunctive relief. 631 F.2d at 190 ("If such a showing is made, the plaintiff will have established a reasonable belief that he is likely to be damaged within the meaning of § 43(a) and will be entitled to injunctive relief, as distinguished from damages, which would require more proof.").

Section 43(a)(1)(B) of the Lanham Act does not cover all speech that is damaging to a competitor; rather, it applies only to misrepresentations made in "commercial advertising or promotion." 15 U.S.C. § 1125(a)(1)(B); see also Fashion Boutique, 314 F.3d at 57. The "touchstone of whether a defendant's actions may be considered 'commercial advertising or promotion' under the Lanham Act is that the contested representations are part of an organized campaign to penetrate the relevant market." Fashion Boutique, 314 F.3d at 57. Although "Section 43(a) of the Lanham Act has been characterized as a remedial statute that should be broadly construed," Gordon & Breach Science Publishers v. AIP, 859 F. Supp. 1521, 1532 (S.D.N.Y. 1994), "Congress, in extending the Lanham Act to product disparagement, made clear that this extension should not be interpreted so as to infringe on free speech protected by the First Amendment," id. at 1533. As Judge Sand explained after reviewing the relevant legislative history in Gordon & Breach, the reach of Section 43(a) "specifically extends only to false and misleading speech that is encompassed within the 'commercial speech' doctrine developed by the United States Supreme Court." Id. at 1533–34, 1536. Commercial speech "is entitled to a lesser degree of protection than other forms of constitutionally guaranteed expression. Accordingly, the government may regulate commercial speech in ways that it may not regulate other speech." *Id.* at 1536 (internal citations omitted).

The Second Circuit has established a three-factor test to determine whether statements constitute "commercial advertising or promotion" under Section 43(a) of the Lanham Act: The statement "must be (1) commercial speech, (2) made for the purpose of influencing consumers to buy defendant's goods or services, and (3) although representations less formal than those made as part of a classic advertising campaign may suffice, they must be disseminated sufficiently to

the relevant purchasing public." <sup>2</sup> *Gmurzynska v. Hutton*, 355 F.3d 206, 210 (2d Cir. 2004) (internal quotation marks and citations omitted) (collecting cases); *see also Enigma Software Group USA, LLC v. Bleeping Computer LLC*, 194 F. Supp. 3d 263, 293 (S.D.N.Y. 2016) (quoting and applying this *Gmurzynska* standard).

Pure "commercial speech" is "speech which does no more than propose a commercial transaction." *Gmurzynska*, 355 F.3d at 210; *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66 (1983) (noting that the "core notion of commercial speech" is "speech which does no more than propose a commercial transaction" (internal quotation marks omitted) (quoting *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976))). A "hybrid' communication, *i.e.*, one that combines commercial and non-commercial elements, may also be considered 'commercial' where (1) it is an advertisement; (2) it refers to a specific product or service; and (3) the speaker has an economic motivation for the speech." *Bleeping Computer*, 194 F. Supp. at 294 (citing *Bolger*, 463 U.S. at 66–67). In *Bolger*, the Supreme Court held that informational pamphlets "discussing the desirability and availability of prophylactics in general or [the defendant's] products in particular" were commercial speech because they were "conceded to be advertisements," contained "reference to a specific product," and the defendant "ha[d] an economic motivation for mailing the pamphlets. *Bolger*, 463 U.S. at 66–67. Even though no one of those factors was

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<sup>&</sup>lt;sup>2</sup> This test "adopts three of the four prongs first described by the Honorable Leonard B. Sand in *Gordon & Breach Science Publishers S.A. v. Am. Inst. of Physics*, 859 F. Supp. 1521, 1535–36 (S.D.N.Y. 1994)." *Boule v. Hutton*, 328 F.3d 84, 91 (2d Cir. 2003). The Second Circuit has repeatedly declined to reach the question whether "the fourth prong from *Gordon & Breach*—that the defendant and the plaintiff be competitors—is necessary to find commercial advertising and promotion." *Id.*; *see also Fashion Boutique*, 314 F.3d at 58; *Gmurzynska*, 355 F.3d at 210. Even if the fourth requirement is necessary, it is not at issue here; there is no debate that ChromaDex and Elysium are competitors.

independently sufficient to place the pamphlets in the category "commercial speech," the combination of the three made them commercial speech "notwithstanding the fact that they contain discussions of important public issues." *Id.* 

Elysium's Counterclaim challenges a specific statement on the Right of Assembly blog, a blog located at the website address right-of-assembly.org. Joint 56.1 ¶ 49. The challenged statement is:

ChromaDex isn't allowed to say that NR treats any disease, because the FDA has not approved that. But the FDA doesn't regulate me, so I am free to tell you that the scientific evidence is growing that NR supplements replenish cellular NAD, which can protect against MANY ailments, including Alzheimer's, Heart Disease, Parkinson's Disease, Breast Cancer, alcohol induced liver poisoning, chemotherapy induced peripheral neuropathy, organ injury from sepsis and in my own experience, Restless Legs Syndrome (RLS). You can find out more here: AboutNAD.com.

Id. Elysium alleges that the statement appears "on upwards of 20 blog posts—posts that were flooded with advertisements for Tru Niagen, and with direct links to purchase the product." Counterclaim ¶ 144. Elysium further asserts that Right of Assembly is "a marketing website for Tru Niagen for which ChromaDex pays commissions to Shelly Albaum for Tru Niagen customers referred through the website." Dkt. No. 249 ¶¶ 19–20, 23.

The challenged statement is not pure commercial speech, i.e., "speech that does no more than propose a commercial transaction." It does not propose a commercial transaction at all, but merely purports to convey information about NR and NR supplements. As ChromaDex points out, the challenged statement is "about the 'scientific evidence' surrounding NR [and] does not refer to Tru Niagen, ChromaDex, or link to any website where Tru Niagen may be purchased." Dkt. No. 262 at 4. The challenged statement, viewed in isolation, also would not constitute "hybrid" commercial speech under the *Bolger* analysis. Even accepting, as the Court must on summary judgment, that the evidence construed favorably to Elysium establishes that the speaker

had an economic motivation for the speech,<sup>3</sup> the challenged statement on its face is not an advertisement and does not refer to any specific product or service. It is a comment on a molecule and on a category of products no different than a comment which one might see made in the public interest with respect to any category of products claimed to have health benefits.

Elysium argues that the Court should analyze the website as a whole to determine whether it is commercial speech, rather than analyzing the challenged statement in isolation. It characterizes Right of Assembly not as a "third-party, noncommercial blog," but rather "as a referral website for Tru Niagen" that "advertises Tru Niagen at the top of every page of its website." Dkt. No. 250 at 18–19.

The law supports the proposition that whether a statement constitutes commercial speech in the first instance and a promotion or advertisement in the second is not to be judged solely by looking at the challenged statement alone and in isolation but also by examining the entire communication in which the statement appears. With respect to commercial speech, *Bolger* itself is illustrative. The Court did not limit its analysis to each sentence in the pamphlets being regulated but addressed the pamphlet as a whole. In the Lanham Act context, as well, courts do not end the analysis with the language that is alleged to be false and misleading but also consider the larger communication in which the statement is located. *See, e.g., Apotex,* 823 F.3d at 66 (examining brochures as a whole); *Gmurzynska,* 355 F.3d at 210–11 (considering whether alleged misrepresentations were actionable under the Lanham Act, and analyzing both the statements themselves and the broader context in which the statements were made—in a museum exhibition catalogue and in a magazine article). A statement that a product has health or other

<sup>&</sup>lt;sup>3</sup> This remains true regardless whether the speaker is properly viewed as Albaum on his own behalf, or Albaum as ChromaDex's agent.

benefits may be considered a public service announcement if it is located in a copy of Consumer Reports. *See Gordon & Breach*, 859 F. Supp. at 1534. It would take on quite a different flavor and the communication as a whole would be regulated by the Lanham Act if it was issued by a person with an economic motive and at the end of the commercial or advertisement touting health benefits, a banner appeared "Buy This Product." *See id.*; *cf. Donini Intern., S.p.A. v. Satec (U.S.A.) LLC*, 2004 WL 1574645, at \*7 (S.D.N.Y. July 13, 2004) (rejecting Lanham Act claim based on allegedly false and defamatory statements appearing in articles in a trade magazine in part because the magazine "is not in the business of selling any goods or services that could have been promoted by statements contained in the articles in question").

Elysium's argument, however, runs afoul of the federal and the local rules regarding summary judgment. A party with the burden of proof may not rely on mere assertion alone when its claim is properly challenged by the movant. Under Federal Rule of Civil Procedure 56(c), it must either cite to "particular parts of materials in the record" including depositions and documents that would create a genuine issue of fact or show that the materials cited do not establish the absence of a genuine dispute. Fed. R. Civ. P. 56(c); see also Jaramillo, 536 F.3d at 145; Wright, 554 F.3d at 266. Under Local Rule 56.1(d), a statement by an opponent to summary judgment "must be followed by citation to evidence which would be admissible, set forth as required by Fed. R. Civ. P. 56(c)." L.R. 56.1(d); see also Holtz, 258 F.3d at 74.

Although Elysium states in its Rule 56.1 statement of additional facts that the blog "has Tru Niagen advertisements at the top of each page that are live links to purchase Tru Niagen" the only evidence to which it points is a screenshot of one page of the Right of Assembly blog that does not contain the challenged statement. See Dkt. No. 245, Ex. UU. Rather, it shows advertisements for Tru Niagen on what appears to be the homepage of the blog, with links to

blog posts in order of recency. *Id.* The single page does not demonstrate that the challenged statement is accompanied by an advertisement for Tru Niagen. ChromaDex pointed out the absence of evidence that the blog statement was commercial speech in its Rule 56.1 statement. ChromaDex 56.1 ¶¶ 19–20. The burden thus fell to Elysium to support its claim. See Jaramillo, 536 F.3d at 145 (stating that, if the moving party meets its burden, "the nonmoving party must come forward with admissible evidence sufficient to raise a genuine issue of fact for trial in order to avoid summary judgment"); Gottlieb, 84 F.3d at 518 (stating that the nonmoving party "cannot defeat the motion by relying on the allegations in [its] pleading, or on conclusory statements, or on mere assertions that affidavits supporting the motion are not credible" (internal citation omitted)). It did not meet that burden. As ChromaDex notes, "Elysium does not provide links to or screenshots of the posts where the above language appeared." Dkt. No. 210 at 7 n.3. Nor does the evidence support Elysium's assertion that there is a reference to Tru Niagen on the top of every page of the website. That assertion is pure *ipse dixit*. Elysium had the opportunity to take discovery. It could have deposed the blogger or presented evidence of what was on the blog as a whole if that evidence supported its claim. In the absence of any such evidence, Elysium cannot withstand ChromaDex's motion for summary judgment on this claim.

Elysium's claim cannot withstand summary judgment for another reason. Elysium has identified no admissible evidence to support the claim that ChromaDex made the challenged statement. The Lanham Act is directed to the "person who . . . uses in commerce" a false or misleading statement in commercial advertising or promotion. 15 U.S.C. § 1125. The language connotes being an active user, not a passive beneficiary. The law ordinarily applies where the challenged statement is made by the defendant and attributed to it; that is the clearest use in commerce. It has been applied in a handful of cases where, even though a statement is not

attributed to the defendant, it is made by an agent of the defendant. See, e.g., Bleeping

Computer, 194 F. Supp. 3d at 269. The theory presumably is that the statutory language carries with it the common law concept that a principal is typically liable for tortious acts committed by its agent within the scope of the agent's authority. See Restatement (Third) of Agency 2,

Introductory Note ("This Chapter states . . . the three distinct bases on which the common law of agency attributes the legal consequences of one person's action to another person."). There are no reported cases where Lanham Act liability is extended to a company that merely benefits from the statement and compensates the author for the statement in the absence of an agency relationship or evidence that it has exercised control over or caused the statement.

In its Rule 56.1 statement, ChromaDex points to the absence of evidence that it made the challenged statement on the Right of Assembly blog. ChromaDex asserts the blog is "the personal blog of an individual named Shelly Albaum." ChromaDex's 56.1 ¶ 19 (citing www.right-of-assembly.org); *see also* Dkt. No. 245, Ex. UU ("Right of Assembly is my personal blog. All opinions are my own."). ChromaDex states that "[t]here is no evidence in the record that ChromaDex controls editorial content, including any at-issue language, on Right of Assembly." ChromaDex's 56.1 ¶ 20. Elysium responds that "Mr. Albaum is acting as ChromaDex's advertising agent," Dkt. No. 250 at 19, and that the Right of Assembly is "a marketing website for Tru Niagen for which ChromaDex pays commissions to Shelly Albaum for Tru Niagen customers referred through the website," Dkt. No. 249 ¶¶ 19–20, 23.

The evidence that Elysium cites fails to create a genuine issue of material fact. An agency relationship exists "when one person (a "principal") manifests assent to another person (an "agent") that the agent shall act on the principal's behalf and subject to the principal's control, and the agent manifests assent or otherwise consents so to act." Restatement (Third) of

Agency § 1.01. Thus, "[a]n essential characteristic of an agency relationship is that the agent acts subject to the principal's direction and control." *In re Shulman Transport Enterprises, Inc.*, 744 F.2d 293, 295 (2d Cir. 1984). If the principal is able to control the actions of the agent, it is not unfair to impose liability on the principal for injury caused to a third party.

The evidence Elysium does not create a genuine issue of fact that Albaum acts under ChromaDex's direction and control. Elysium cites an undated slide deck on ChromaDex's affiliate program which includes Albaum as one of ChromaDex's affiliates, Dkt. No. 251, Ex. SS,<sup>4</sup> but the deck does not support the proposition that ChromaDex enjoyed any agency relationship with Albaum. It indicates only that at some point in time (either before or after the challenged statement) a marketing consultant—not Albaum—was asking "[w]hat placements can be optimized" and "[w]ill she [sic] work with you to ad [sic] content regularly." Rather than support Elysium, the deck supports the inference that Right of Assembly did not report to ChromaDex and that it did not even regularly work with the company in creating content. Dkt. No. 263 ¶ 23. Elysium also cites to evidence that the Right of Assembly blog holds Albaum out as a ChromaDex marketing affiliate. Dkt. No. 245, Exs. VV—WW (screenshots from the Right

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<sup>&</sup>lt;sup>4</sup> ChromaDex argues that this slide deck is unauthenticated and inadmissible. Under Federal Rule of Evidence 901(a), the requirement that documents be authenticated "is satisfied by evidence sufficient to support a finding that the matter in question is what the proponent claims." F. R. Evid. 901(a). "[T]estimony of a witness with knowledge provides appropriate authentication." *Commercial Data Servers, Inc. v. IBM Corp.*, 262 F. Supp. 2d 50, 58 (S.D.N.Y. 2003). Elysium offers this slide deck along with a declaration from its attorney that it "is a true and correct copy of ChromaDex's "TRU NIAGEN Affiliate Program Audit" produced by ChromaDex in this action bearing the Bates numbers CDX\_00077392-410." Dkt. No. 251 ¶ 11. This declaration "constitutes testimony by a witness with knowledge of what the firm received from its opponent in response to legitimate discovery requests" and therefore properly authenticates the document. *IBM*, 262 F. Supp. at 58–58; *cf. Wahhab v. City of New York*, 386 F. Supp. 2d 277, 291 (S.D.N.Y. 2005) (holding that where "[t]he documents in question are not sworn, they do not contain an affirmation indicating the truth of their contents, nor do they assert a basis in personal knowledge," they "do not qualify as evidentiary proof in admissible form" and thus "will not be considered by this court in this summary judgment ruling").

of Assembly website indicating that it is a ChromaDex marketing affiliate). But that Right of Assembly calls Albaum a marketing affiliate, without more, does not support the notion that ChromaDex holds him out publicly as a marketing affiliate or that ChromaDex exercises any authority over the speech that Albaum makes or does not make.

Finally, Elysium cites to deposition testimony of then–ChromaDex CEO Frank Jaksch that Albaum is a ChromaDex shareholder and that characterizes an affiliate relationship as one where "somebody else would post a small ad or whatever you want to call it, something on the website that if somebody clicked on it would drive them to our website if they bought that product. Where that traffic came from or who had that ad posted would be paid some form of a commission." Dkt. No. 251, Ex. TT at 141–46. Elysium also cites to two emails between Albaum and Jaksch in one of which Albaum reaches out to Jaksch with a blog article (albeit not one with the challenged statement) that he states he chose not to post but will post the article if "Jaksch wants me to" and requests that Jaksch "consider these ideas seriously," and in another of which Jaksch reaches out to Albaum to flag the filing of ChromaDex's citizen petition. *Id.* ¶ 24 (citing Dkt. No. 251, Ex. XX–YY).

That evidence does not establish that ChromaDex had a relationship with Albaum or with Right of Assembly where it was able to exercise direction or control over Albaum's communications. That Albaum was a shareholder of ChromaDex gave him an independent economic incentive to tout its products no different than the economic incentive that any investor, whether an activist institutional investor or a retail investor, might have to promote the products of a company in which it has a financial interest. That interest does not give the company whose shares are owned the ability to exercise direction and control over its shareholder nor does it make the company responsible for every one of the shareholder's

statements. Likewise, the fact that ChromaDex might reward Albaum or any other third party for steering business ChromaDex's way does not establish that ChromaDex has the ability to exercise any control or direction over the statements that Albaum might make. A whole industry exists of social media influencers, who create their own content touting products and receive commission on sales of those products that stem from their advertising. A claim might lie directly against such persons whether under federal law or the state law of trade defamation if they make a false and misleading statement. But in the absence of evidence that an influencer is making the statement on behalf of the defendant or at the defendant's direction or under its control rather than simply for its own benefit, the company cannot be held liable on a principal—agent theory. See In re Fyre Festival Litigation, 399 F. Supp. 3d 203, 213 (S.D.N.Y. 2019) (holding that "[c]ertain allegations reference statements made by online influencers who are not defendants . . . cannot form the basis of a fraud claim" against the defendants because they are not "attributable to defendants").

The emails reflect that Albaum believed he had the authority to make his own independent decisions whether to post or not, even if he might—based on the exercise of his own discretion—choose to follow a request of Jaksch. They do not reflect that Jaksch made such a request as to any communication or that Albaum honored it. To the extent the emails show ChromaDex communicating with a shareholder who—in turn—was communicating with the public, companies not infrequently communicate with shareholders and other third parties who might write about the company or its products. Both the company and its shareholder have an interest in getting the communication right. *Cf. Elkind v. Liggett & Myers, Inc.*, 635 F.2d 156, 163 (2d Cir. 1980) (affirming lower court's finding that defendant did not "place its imprimatur, expressly or impliedly," on projections even though it "did examine and comment on a number

of reports" and "made suggestions as to factual and descriptive matters in a number of the reports it reviewed"), *superseded on other grounds as stated in Acticon AG v. China North East Petroleum Holdings Ltd.*, 692 F.3d 34 (2d Cir. 2012). But that the fact that the company might communicate with a person who later writes about the company or its product does not make the company liable under the Lanham Act. To so penalize the company or its executive officers based solely on a company's executives private communications with the company's shareholder would strain both the Lanham Act and the First Amendment.

The principal case cited by Elysium highlights the deficiency of Elysium's claim. In *Enigma Software Group USA, LLC v. Bleeping Computer LLC*, a computer software company asserted a Lanham Act false advertising claim, for statements made about it and its product on a computer support website owned and operated by the defendant.<sup>5</sup> 194 F. Supp. 3d at 269. The court concluded that the allegations regarding a moderator on the site, Quietman7, "plausibly support the conclusion that Quietman7 was acting, at a minimum, as [defendant's] implied agent when he posted the allegedly offending content." *Id.* at 274–75 (internal quotation marks, citations, and alterations omitted). Quietman7 was publicly designated by the defendant as a "Global Moderator" and "Advisor," which are "the second and third highest 'staff member' positions within the [defendant] member group hierarchy"; publicly accepted those appointments and held himself out on the website as a member of the staff; was, as a staff member of the defendant, "authorized and expected to post in [defendant's] forums," and "directed to recommend and promote certain products for which [the defendant] receives commissions and to discourage use of other products from which it does not receive commission"; and as an

<sup>&</sup>lt;sup>5</sup> The court thus did not consider whether the same claim could be asserted against the plaintiff's direct competitor with whom the defendant had an affiliate relationship, a much closer parallel to this case. *See id.* at 271.

"Advisor" was "touted as [an] expert[] who can be trusted to give correct and understandable answers to [defendant's] member's questions," and as a "Global Moderator" was "authorized to enforce the rules of [the defendant's website], to answer questions (or help people with problems), and to suspend forum posting privileges of members who violate forum rules." *Id*. In those circumstances, it was fair to believe that a principal–agent relationship existed.

There are no similar facts here that could support a finding of an agency relationship between ChromaDex and Albaum. No evidence suggests that ChromaDex controls or even monitors any of the content on the Right of Assembly webpage, let alone the challenged statements themselves. No evidence suggests that ChromaDex publicly held out Albaum to be a member of its staff, endorsed to make statements on his blog that ChromaDex attested were "correct." No evidence suggests that Albaum publicly held himself out to represent ChromaDex; in fact, his blog explicitly disclaims any such representation.

Rather, the record reflects only that Albaum is a ChromaDex shareholder and a successful member of ChromaDex's marketing affiliate program who receives a commission for sales of Tru Niagen through his webpage. As in *Bleeping Computer*, if Elysium has a claim based on alleged false advertising on the blog, that claim would lie against Right of Assembly or Albaum, not against ChromaDex.

### B. Falsity

Both parties' motions for summary judgment focus heavily on the falsity element of the Lanham Act. Elysium moves for summary judgment, asking this Court to dismiss ChromaDex's "claims in its Second Amended Complaint . . . in their entirety" because "ChromaDex cannot show that any of Elysium's alleged misstatements are false or misleading." Dkt. No. 222 at 1, 11. ChromaDex, in turn, moves for summary judgment on Elysium's counterclaims because "Elysium cannot meet its burden of showing that any of ChromaDex's purported advertising

claims are literally false." Dkt. No. 210 at 1. Elysium also moves for summary judgment on the portion of its Counterclaim that relates to what it terms the "Counterfeit Page," arguing that "the statements in the Counterfeit Page . . . are literally false or false by necessary implication . . ." Dkt. No. 222 at 25. The Court addresses the arguments as to falsity in these two motions in turn.

### 1. ChromaDex's Complaint

Elysium's motion for summary judgment on ChromaDex's claims as to the falsity element of the Lanham Act is granted in part and denied in part. Elysium's motion is granted with regard to ChromaDex's claims about statements regarding the safety and purity of Basis, statements that Basis is clinically proven to raise NAD+ levels based on the Dellinger Study, statements that Basis is the "first" such supplement, statements regarding the expected synergistic effects of combining NR and PT, statements regarding FDA regulation of Basis, statements regarding Elysium's role in the research behind Basis, statements that Elysium is the exclusive licensee of an NR patent, statements regarding the amount of NR in Basis, and statements about Elysium's Scientific Advisory Board and client testimonials. Elysium's motion is denied with regard to the statement that Basis is the "only" supplement proven to increase and sustain NAD+ levels in humans.

### a. Statements Relating to Safety and Purity of Basis

# i. Statements Regarding the Dellinger Study

As it has been limited through the briefing, ChromaDex's allegations that Elysium made false statements that Basis is "safe" and "pure," Dkt. No. 222 at 11, have been reduced to one statement. On its website, Elysium made the following claim:

• "Basis Increases NAD+ Levels, Safely and Sustainably," and the Dellinger Study "confirmed the safety of Basis, demonstrating that participants experienced no serious adverse effects and that Basis continues to be safe for daily use as determined by standard safety measures." Dkt. No. 255 at 16 (quoting SAC, Exs. G, N).

ChromaDex alleges that the statement is literally false; it alleges that Basis did not increase NAD+ levels safely and the Dellinger Study did not confirm the safety of Basis. Dkt. No. 255 at 16.

"One kind of literally false claim is a claim of test-proven superiority. The premise is that the 'defendant's advertisement explicitly or implicitly represents that tests or studies prove its product superior' . . . . " Apotex, 823 F.3d at 63 (internal alterations omitted) (quoting Castrol, Inc. v. Quaker State Corp., 977 F.2d 57, 63 (2d Cir. 1992)). The claim challenges whether a cited test supports the underlying proposition, not the truth or falsity of the underlying proposition itself. Accordingly, to succeed on a claim of false advertising for statements based on clinical studies, the plaintiff must demonstrate that the relevant study is "not sufficiently reliable to permit one to conclude with reasonable certainty that [it] established the claim made." McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co., 938 F.2d 1544, 1549 (2d Cir. 1991); McNeil-PPC, Inc. v. Pfizer Inc., 351 F. Supp. 2d 226, 248–49 (S.D.N.Y. 2005). "The fact-finder's judgment should consider all relevant circumstances, including the state of the testing art, the existence and feasibility of superior procedures, the objectivity and skill of the persons conducting the tests, the accuracy of their reports, and the results of other pertinent tests." Proctor & Gamble Co. v. Chesebrough-Pond's Inc., 747 F.2d 114, 119 (2d Cir. 1984). If the test is not sufficiently reliable to permit one to conclude with reasonable certainty that the test established the claim made, then the advertising assertion that the test proved or established the proposition is false.

On its face, the Dellinger Study says what Elysium claims it said. As noted above, the study showed a dose-dependent increase in NAD+ levels sustained over the course of the trial. Dkt. No. 229 ¶ 12, Ex. C ("Dellinger Study"). In the group receiving a single dose of Basis for

eight weeks ("NRPT 1X"), NAD+ levels increased by approximately 40% as compared to the placebo baseline, and in the group receiving a double dose of Basis for eight weeks ("NPRT 2X"), NAD+ levels increased by approximately 90%, as compared to the placebo baseline. Dellinger Study at 1. In both groups, the increased NAD+ levels were sustained throughout the eight-week study. *Id.* Moreover, the study reported "no serious adverse events," and concluded that "a repeat dose of NRPT is a safe and effective way to increase NAD+ levels sustainably." *Id.* The study thus supports Elysium's claim—that "Basis Increases NAD+ Levels, Safely and Sustainably," and that the Dellinger Study "confirmed the safety of Basis."

The burden is on ChromaDex at summary judgment to adduce evidence from which a factfinder could determine that the Dellinger Study was not sufficiently reliable to "establish the proposition for which [it was] cited." *Apotex*, 823 F.3d at 63 (quoting *Castrol*, 977 F.2d at 63). ChromaDex has identified no evidence to support that the Dellinger Study is not sufficiently reliable to permit one to conclude with reasonable certainty that it establishes the proposition for which it was cited—that Basis safely and sustainably raises NAD+ levels. It identifies no evidence regarding the state of the testing art, the existence and feasibility of superior procedures, the objectivity and skill of the persons conducting the tests, the accuracy of the reports, or the results of other pertinent tests that would call into question the reliability of the Dellinger Study's conclusions.

ChromaDex relies exclusively on the fact that the Dellinger Study found that the groups taking Basis experienced increases in LDL-cholesterol and that the study concluded that further research was needed to fully understand whether these changes were attributable to Basis. The study stated:

Total cholesterol and LDL-cholesterol showed within-group increases at day 30 (NRPT 2X) and day 60 (NRPT 1X and NRPT 2X) compared to baseline. The

increase in total cholesterol in the NRPT 1X group compared to the placebo group was not significant at day 30 or day 60. The increase in LDL cholesterol in the NRPT 1X group compared to the placebo group was approximately 3% at day 30 and 3.5% at day 60. Larger increases in total cholesterol and LDL cholesterol were observed in the NRPT 2X group. However, there were significant across group differences in total and LDL cholesterol at baseline mainly due to lower levels in the placebo group, confounding the interpretation of the study data.

Thus, we stratified the three treatment groups by BMI and reanalyzed the data. Subjects in the NRPT 1X group with normal BMI<sup>6</sup> (18–25) showed no significant increases in LDL cholesterol at day 30 or day 60. Subjects in the NRPT 2X group with normal BMI did show increases in LDL cholesterol at day 30 and day 60. Subjects in the overweight category (BMI 25–32) showed increases in LDL cholesterol at day 30 and day 60 in both the NRPT 1X and NRPT 2X groups. However, overweight subjects in the placebo group also showed a significant increase at day 60. Overall, these findings suggest a small but significant increase in cholesterol may occur at the normal dose of NRPT, at least for people with a higher than normal BMI. Further studies are needed with increased number of subjects to determine if the small changes observed are real or due to chance.

### Dellinger Study at 5.

The evidence that the Dellinger Study itself found a 3.5% increase in LDL cholesterol in the group taking Basis does not call into question the reliability of the conclusion reached by the authors of that same study that Basis is safe. In particular, ChromaDex identifies no evidence either from fact or expert witnesses that would support the conclusion that Basis caused the increase in cholesterol. From the evidence before the Court, it would require an unfounded leap to infer that Basis is unsafe simply because in the study there was a correlation between taking Basis and a slight increase in LDL cholesterol. *Cf. In re Mirena IUS Levonorgestrel-Related Products Liab. Litig.*, 387 F. Supp. 3d 323, 337-38 (S.D.N.Y. 2019) (requiring expert evidence of general and specific causation in products liability case). To conclude otherwise is to fall prey to the "post hoc, ergo propter hoc" fallacy—that simply because one event follows another one can conclude that the first event caused the second.

<sup>&</sup>lt;sup>6</sup> Body mass index, *see* Dellinger Study at 7.

More importantly, ChromaDex identifies no evidence that the increase in cholesterol reported in the Dellinger Study says anything about the safety of Basis. To the contrary, Elysium points to various pieces of evidence that show both that Basis did not necessarily lead to the increase in LDL and that the increase in LDL did not make Basis unsafe. That evidence includes the declaration of Marguerite Brackley, an independent medical consultant retained by Elysium, stating both that "[n]umerous factors unrelated to Basis could explain the LDL results, including the very small sample sizes, differences in baseline characteristics of the patients in the different trial arms, and normal variations in LDL levels," and that "there was no indication that any increase in LDL was *clinically* significant, i.e., that it had any health consequences for the patients in the study." Dkt. No. 226 ¶ 4. It also includes Brenner's testimony at deposition that LDL fluctuates day to day in a healthy person and "can fluctuate . . . 5 or 10 percent," Dkt. No. 223, Ex. 1 at 179, i.e., that the increase of 3.5% in the Dellinger Study is consistent with normal fluctuations and that a person could experience the increase in LDL reflected in the study while still remaining healthy. Elysium also points to the deposition testimony of Kurt Hong, who was retained by ChromaDex as an expert witness, that when he was evaluating the Dellinger Study, he was not able to determine how likely the participants were to have an adverse health effect based on the increase in their LDL levels. Dkt. No. 223, Ex. X at 157. Finally, Elysium points to testimony that it conducted a clinical study which is not yet published, but the details of which are available on clinicaltrials.gov, in which participants who took Basis for ninety days showed no statistically significant change in LDL levels. Dkt. No. 257, Ex. 4 at 168–71; Ex. 7 at 142– 45.

ChromaDex's argument to the contrary relies on "unsubstantiated speculation." *F.D.I.C.*, 607 F.3d at 292. It fails to identify anything in the record inconsistent with that evidence or that

would create a genuine issue of fact as to whether the Dellinger Study was not sufficiently reliable to permit one to conclude with reasonable certainty that Basis was safe. It does not identify evidence from which a jury could conclude that Basis caused the increase in LDL levels or that even if it did, such increase rendered Basis unsafe. Thus, there is no evidence to dispute what the Dellinger Study authors themselves reported and what Elysium then relayed—that the Dellinger Study confirmed that Basis is safe.

ChromaDex points to "numerous customer communications with complaints about increased LDL cholesterol in customers taking Basis." Dkt. No. 355 at 11 (citing Dkt. No. 257, Ex. 23). In particular, Exhibit 23 contains forty-one "Zendesk tickets," ranging in dates from 2016 to 2020, each of which involves a customer communication referencing cholesterol or LDL. Dkt. No. 257, Ex. 23. In some cases, the consumers claim that Basis raised their cholesterol or that their LDL levels increased after taking Basis, regardless of causation, see, e.g., id. at 2 ("affected hers and her husband's cholesterol and caused it to increase"); id. at 3 ("After taking basis for 6 months, my LDL levels in bloodwork came back much higher."); in others, the consumer simply raises a concern about the possibility of Basis affecting their cholesterol, see, e.g., id. at 5 ("I am concerned about taking Elysium because it contains pterostilbene which has been shown to increase LDL."). The evidence is not surprising and not inconsistent with the Dellinger Study— it does not create an issue with respect to the reliability of the Dellinger Study. The Dellinger Study found that some persons on Basis experienced increases in LDL. It thus stands to reason that there would be some persons who experienced increases in LDL while on Basis who complained about that increase. But it does not follow from the complaints that the increase was caused by Basis or that it led to an unsafe condition. The complainants did not know the cause of the increase in their LDL. It is not disputed that that the forty-one tickets were among the 525,037 customer messages received by Elysium during this four-year period. Dkt. No. 273 at 7 (citing Dkt. No. 270, Ex. RRR). ChromaDex provides no context for or any other information about these messages. It does not provide information regarding "the source, content, and context of the reports." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 43 (2011). There is no information to support that the reports of an increase in LDL or cholesterol were accurate, that the increase was sufficient to create safety concerns, or that the increase was related in any way to Basis as opposed to some other health condition of the comment author. Even assuming that the reports were reliable and that the increase in cholesterol was significant and sustained, "the mere existence of reports of adverse events... says nothing about whether the drug is causing the adverse events." *Id.* at 44. Pointing to a few dozen customer complaints referencing cholesterol, in context of the hundreds of thousands of customer messages received during this time, is not sufficient to create a triable issue of fact regarding the reliability of the Dellinger Study.

ChromaDex also claims broadly that Elysium's scientific advisory board ("SAB") "recommended eliminating PT from Basis because 'a 10% increase in cholesterol is not trivial," and that "there was Board consensus that, at the very least, additional studies were needed" but that "Elysium has not published any follow-up studies on the effect or either PT or the NRPT combination on LDL levels." Dkt. No. 255 at 12 (citing Dkt. No. 257, Ex. 24). The opponent of summary judgment may not rely simply on assertion but most point to "particular parts of materials in the record" to support the assertion. *See Wright*, 554 F.3d at 266 ("When a motion for summary judgment is properly supported by documents or other evidentiary materials, the party opposing summary judgment may not merely rest on the allegations or denials of his pleading; rather, his response, by affidavits or otherwise as provided in the Rule, must set forth

'specific facts' demonstrating that there is 'a genuine issue for trial.'" (quoting Fed. R. Civ. P. 56(e))). The evidence that ChromaDex cites does not support its assertions. The only evidence ChromaDex cites is an email from one board member who did not attend the meeting where the results were discussed who, after stating that "a 10% increase in cholesterol is not trivial," adds "I may misunderstand some of the results or facts." Dkt. No. 257, Ex. 24 at 2. The Dellinger Study did not show a 10% increase in cholesterol in the recommended dosage; it showed that increase in the group taking twice the recommended dosage. *See* Dkt. No. 257, Ex. 4 at 159–60. There is no evidence that the SAB recommended eliminating PT from Basis. As to the supposed consensus that additional studies were needed, that was the view of the Dellinger Study itself. It is not inconsistent with its conclusion, nor does it call into question its methodology.

ChromaDex points to no evidence suggesting that the study's conclusion—that, considering all the results including the increase in LDL levels, Basis safely and sustainably increased NAD+ levels—was false or unreliable, and therefore that Elysium's citation to that conclusion in its advertising was, by extension, false. As such, there is no triable issue of fact, and Elysium is entitled to summary judgment on this claim.

### ii. Other Statements Regarding Safety and Purity

In its complaint, ChromaDex initially challenged other of Elysium's statements regarding safety and purity including:

• Elysium's statement in a *CEO/CFO Magazine* article published on or around December 11, 2017 that "[w]e also needed to develop the supply chain so that we have the highest quality material possible and in the purest form possible." Dkt. No. 222 at 11 n.1 (quoting SAC ¶ 98, Ex. P).

<sup>&</sup>lt;sup>7</sup> Moreover, Elysium did conduct a follow-up study which tracked the effects of Basis on cholesterol levels over time, as recommended by the advisory board. *See* Dkt. No. 257, Ex. 4 at 168–71.

- Elysium's statement in a *Proof Wellness* article published on or around August 13, 2019 that "we wanted to set a new standard for quality and purity for consumer products by establishing a supply chain that exceeded guidelines set by the FDA and was validated by third-parties." *Id.* (quoting SAC ¶ 98, Ex. EE).
- Elysium's statement in a *Techcrunch* article published on or around August 29, 2019 that "[b]y and large [Basis] is one of the safest products we've ever seen." *Id.* (quoting SAC ¶ 114, Ex. GG).
- Elysium's statement first published on its website on or around February 23, 2019 that Basis is "Setting A New Standard o[f] Quality and Purity." *Id.* (quoting SAC ¶ 98, Ex. G).

ChromaDex initially alleged that Elysium's claims regarding the "quality" and "purity" of its ingredients were false because Elysium's methods of manufacturing "caused high levels of acetamide, a known carcinogen, to be present in Basis shipped to consumers." SAC ¶ 99. That allegation, however, did not survive discovery. As Elysium points out, the undisputed evidence establishes that it "eliminated all acetamide from its manufacturing process in or about August 2017," and that it "made its Safety and Purity Claims *after* acetamide was eliminated from the ingredient." Dkt. No. 222 at 12 (citing Dkt. No. 227 ("Morris Decl.") ¶ 7, Ex. A). There is no other basis ChromaDex has asserted for challenging the truth of the statements regarding quality and purity. Thus, Elysium is entitled to summary judgment.

In any event, ChromaDex does not defend against the argument by Elysium that the statements are either true or are not literally false and thus the claims are deemed abandoned. *See, e.g., Shenk v. Karmazin*, 868 F. Supp. 2d 299, 311 n.12 (S.D.N.Y. 2012) ("While [the plaintiff] originally alleged in his complaint that the defendants breached their fiduciary duties ..., he has not responded to defendant's arguments on summary judgment. Accordingly, he has conceded that defendants are entitled to summary judgment on this claim for breach." (citing *Taylor v. City of New York*, 269 F. Supp. 2d 68, 75 (E.D.N.Y. 2003) ("Federal courts may deem a claim abandoned when a party moves for summary judgment on one ground and the party

opposing summary judgment fails to address the argument in any way."))); *Douglas v. Victor Capital Group*, 21 F. Supp. 2d 379, 393 (S.D.N.Y. 1998) (deeming claims alleged in the complaint abandoned where "Defendants' summary judgment motion specifically addressed all of these claims," but the plaintiff's "opposition papers, however, addressed none of these claims," and collecting cases where other courts have similarly deemed claims abandoned for failure to defend them in opposition to summary judgment).

#### b. Statements Regarding Elysium's Clinical Studies

i. "Basis is clinically proven to raise NAD+ levels based on the Dellinger Study"

ChromaDex also alleges that a "key advertising claim . . . that Basis is clinically proven to raise NAD+ levels based on the Dellinger Study" is literally false because at the time it was made Elysium had ceased to use ChromaDex's Niagen and was using a different source of NR for Basis and "the Dellinger Study was conducted on ChromaDex's ingredients, not Elysium's." Dkt. No. 255 at 15. ChromaDex makes two related arguments: (1) because Elysium had started using a different source of NR and PT after the time of the Dellinger Study, its statements based on reports conducted on the earlier version of the product are necessarily false; and (2) the statements give consumers "the false impression that its clinical trials were conducted on the same ingredients in Basis today." SAC ¶ 63(d)(i).

As with ChromaDex's prior challenge to the Dellinger Study, to succeed in its claim, ChromaDex must demonstrate that the study is "not sufficiently reliable to permit one to conclude with reasonable certainty that [it] established the claim made." *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d at 1549; *McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F. Supp. 2d at 248–49. The burden, therefore, is on ChromaDex to present evidence sufficient to create a jury issue that the Dellinger Study is not sufficiently reliable to permit one to conclude with

reasonable certainty that it establishes that Basis, as formulated at the time of the statements at issue, raises NAD+ levels. ChromaDex has not identified any such evidence.

ChromaDex argues that because at the time the trial was conducted. Elysium was sourcing its NR and PT from ChromaDex, but later sourced those ingredients from other suppliers, the study no longer reliably demonstrates anything about Basis as currently sourced. However, there is no evidence to suggest that the NR Elysium used after ChromaDex was no longer its supplier was anything other than materially identical from a functioning, safety, and efficacy standpoint to the NR that it sourced from ChromaDex at the time of the study. Dkt. No. 273 at 8–9. To the contrary, Dr. Claire Kruger, the managing partner of Spherix Consulting Group, ChromaDex's regulatory consultant, see Dkt. No. 222 at 13 n.2, testified at deposition that the NR molecule is the same in nature and in ChromaDex's NR. Dkt. No. 223, Ex. W at 49– 52. In addition, Morris, Elysium's Chief Product Officer, stated that the NR molecule in synthesized NR is the same as in nature. Morris Decl. ¶ 5. Robert Martin, a former head of the FDA's GRAS department, also testified that "[c]omparing the specifications listed for ChromaDex's NR and Elysium's NR and the certificates of analysis for both of them, one reaches the conclusion that the two products are essentially the same," and "pretty much are equivalent." Dkt. No. 274, Ex. TTT at 121–24.

In response to this evidence, ChromaDex makes the general assertion that "a finished product includes not just active ingredients (or the same 'molecules'), but impurities resulting from the manufacturing process." Dkt. No. 255 at 16. It points to the expert report of Dr. Steven M. Weisman, an expert retained by ChromaDex to provide opinions and testimony about FDA regulation of dietary supplements. Dkt. No. 230, Ex. 11. Weisman opines that Elysium could not rely on ChromaDex's GRAS status to support that Elysium's NR was GRAS, because

"properties may not match the information considered in a prior GRAS assessment, rendering the previous determination of GRAS status inapplicable. GRAS conclusions can only apply to ingredients from other companies if the ingredients are manufactured in a way that is consistent with the existing notification and they meet the listed specifications." *Id.* at 20. He notes that "in their GRAS assessment, Elysium included a chart comparing the specifications for Elysium's NR and ChromaDex's NR, which demonstrates important differences in the specifications, solvents, by-products (including acetamide), and impurity specifications," and includes the chart in his report. *Id.* at 21–22. He concludes that "Elysium could and should not have relied upon the NIAGEN® GRAS assessment for assurance of safety given the differences in specifications and impurity profiles." *Id.* at 23.

For two reasons, Weisman's opinion fails to create a triable issue of fact as to whether the change from ChromaDex's NR to Elysium's NR renders the Dellinger Study insufficiently reliable to support claims about Basis as currently formulated. First, at deposition, Weisman was asked about these differences in specifications and ultimately admitted that he did not know whether they had any safety implications whatsoever. He stated: "I don't know if they're meaningful from a safety perspective, but those are clearly differences in the specifications that could infer differences — a difference in the product that could confer a difference in safety. I'm not rendering an opinion as to whether they do or they don't." Dkt. No. 257, Ex. 34 at 118. It thus would require a guess for the jury to determine the differences were safety related—a guess that Weisman himself was unwilling to hazard.

Second, Weisman's opinion was limited: He opined simply that for the purposes of a GRAS assessment, differences in manufacturing *may* create differences that could be relevant to safety, and thus one manufacturer cannot simply rely on a different manufacturer's GRAS

assessment. Weisman did not opine—nor was he asked to—that these changes in byproduct specifications mean anything about the efficacy or functioning of the ingredient. In other words, Weisman's opinion and testimony is simply that ChromaDex's NR and Elysium's NR had differences in their specifications due to their manufacturing; he does not opine as to whether those differences were actually material to safety—and Elysium points to evidence that they were not—nor does he opine even that they may have caused differences as to the efficacy or functioning of the ingredients. A party opposing summary judgment must demonstrate more than "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus.*, 475 U.S. at 586. Weisman's testimony does not suggest that there was any *actual* difference between the products in terms of safety, efficacy, or functioning, just that there *may* have been a difference—and Elysium points to ample evidence that there was not.

ChromaDex also cites to two out-of-context statements by Elysium's CEO that speak to the dangers of selling products that have not been tested but those statements do not refer to (i) any flaws with the Dellinger Study, (ii) a view that Elysium's NR is any different from ChromaDex's NR, or (iii) concerns that results of a study conducted on Basis using ChromaDex's NR would not be equally applicable to Basis using Elysium's own NR:

- "In a lot of these established categories take prenatal there's great literature supporting the use of folic acid. There's [sic] companies that sell products around that. But they'll make unique claims or link to literature that's been done by other companies on other formulations or other delivery methodologies. Those can be dangerous. The data might appear to be good but in fact their own product hasn't been tested." SAC, Ex. GG at 9.
- "Often, in the rare case where a consumer-facing company cites clinical trial research, they are leveraging the work of others and, almost always, the formulation, dosage, and delivery method are entirely different. While something like that would be obvious to any scientist or clinician, it's a practice that's clearly meant to mislead consumers into a false sense of security that we refused to perpetuate." SAC, Ex. EE at 10–11.

Neither of these statements provide any support for the proposition that Elysium's study, conducted on their own product, is no longer reliable to show the efficacy of that product when the only difference between the product as tested and the product as currently sold is the sourcing of the ingredients, but not their formulation, characteristics, functioning, or efficacy.<sup>8</sup>

Thus, ChromaDex is left only with the proposition that a company that has a study done of its product using an ingredient sourced from one company must as a matter of law cease referring to the results of that study when it starts sourcing, and using in identical quantities, a

<sup>8</sup> ChromaDex also cites several cases to support its proposition that "Elysium was required, at the very least, to confirm the results" of the Dellinger Study after it changed its suppliers; none of those cases suggests that a manufacturer of a product is required, any time it changes the sourcing of an ingredient in an otherwise-identical formulation, to either abandon any claims based on its previously-conducted studies or to conduct new studies to confirm that the change in sourcing did not change the results. In Vidal Sassoon, Inc. v. Bristol-Myers Co., study participants who rated a shampoo were allowed "to use other brands while they were testing [the subject shampoo]," which meant that "the women's responses may not accurately reflect their reaction to [the subject shampoo] as distinct from other shampoos." 661 F.2d 272, 275, 277–78 (2d Cir. 1981). This potential methodological flaw in the way the study was conducted has no bearing on whether a properly-conducted study is rendered inapplicable if a company changes the sourcing of its ingredients. In *Upjohn Co. v. Riahom Corp.*, the challenged study was "conducted on the Italian version of [the product], which has a different concentration of [the active ingredient] than the [defendant's version of the product]." 641 F. Supp. 1209, 1244 (D. Del. 1986). As such, the court reasoned that "[t]he Italian tests therefore may be totally irrelevant as to the safety of the [defendant's] product." Id. Here, in contrast, there is no allegation that the formulation of Basis is any different now than it was when the Dellinger Study was conducted, or that it contains a different amount of any ingredient. It is merely the sourcing of the ingredients that has changed; *Upjohn* does not suggest that in such a situation the study becomes irrelevant. In Burndy Corp. v. Teledyne Indus., Inc., the defendant marketed connectors it sold as compliant with certain agency standards; when it began marketing them as such, the components did result in connectors that were compliant with those standards, but subsequently the components were down-sized and as a result the connectors were no longer compliant. 584 F. Supp. 656, 660-61 (D. Conn. 1984). The court found that "[d]own-sized connectors did not comply with the . . . standard and thus they were not the product approved by the [agency]. Holding them out to be [agency] approved constituted a false representation." *Id.* at 662. Once again, the problem with the representation is not that the sourcing of the components had changed since the approval but rather that the specifications of the components had materially changed such that the product was no longer the same and no longer compliant with the standards; if the sourcing had changed but the specifications had not, the court's reasoning in finding that the representations were false would not have applied.

materially identical ingredient from a different company. Its motion necessarily rests on the proposition that such a change in ingredient is alone sufficient to support a jury verdict that the test is not reliable and that the sponsor's invocation of the report is false and misleading. It cites no law to support such a contention. The proposition—which would mean that a company which once uses a particular supplier must forevermore use that same supplier on pain (if it does not do so) of being in violation of the Lanham Act—finds no home within any of the case law under the Lanham Act. It would present every company that does not manufacture all of its source ingredients with the Hobson's Choice of being locked into its prior suppliers, no matter how extortionate the demands they make or whether they are able to sell, or being silent regarding the outcome of a study, the results of which would be of consumer interest. In the absence of anything more, it is not sufficient to create a genuine issue of fact. ChromaDex therefore presents no triable claim for relief.

## ii. "Basis is the first and only supplement clinically proven to increase and sustain NAD+ levels"

ChromaDex also alleges that Elysium's statement that "Basis is the first and only supplement clinically proven to increase and sustain NAD+ levels" is literally false. The statement appears on Elysium's website.

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<sup>&</sup>lt;sup>9</sup> In its summary judgment papers, ChromaDex alleges that Elysium also stated that "Basis is the first and only supplement clinically proven to increase NAD+ levels," without the "and sustain" qualifier. Dkt. No. 255 at 18 (quoting Dkt. No. 257, Ex. 29). Basis disputes that it ever made the statement without the "and sustain" qualifier, but it does not dispute the authenticity of the Facebook advertisement to which ChromaDex cites that contains the statement. As Elysium pointed out at oral argument, however, ChromaDex's Complaint cites only the version of the statement with the "and sustain" qualifier. Oral Argument Tr. at 54; see also SAC ¶ 63(a)(i). The Court thus considers only the statement that was actually pled in ChromaDex's Complaint. ChromaDex is not entitled to a trial on a claim it did not plead. The complaint in a Lanham Act action is not a mere formality that opens the door to trial on any similar—but not identical—misstatements a party later discovers. If ChromaDex believed the statement without the "and sustain" qualifier was false and that it was injured by it and wished to assert a claim, it could have moved to amend its Complaint and thus given Elysium notice of the allegation and an

There is no genuine dispute that Basis was the "first" supplement clinically proven to increase NAD+ levels. It preceded Tru Niagen by two years. Joint 56.1 ¶¶ 5, 22. ChromaDex identifies no other supplement introduced earlier than Basis that was clinically proven to increase NAD+ levels. <sup>10</sup>

ChromaDex argues, however, that Elysium's claim that Basis is the "only" supplement proven to increase and sustain NAD+ levels in humans is false—and thus that Elysium is not entitled to summary judgment on this claim—because at the time the statement was made, Tru Niagen was clinically proven to increase NAD+ levels in humans.

ChromaDex bases its argument on two propositions. First, it points to the Trammell Study which studied Niagen and demonstrated that Niagen raised NAD+ levels and to the Dellinger Study of Basis (which used ChromaDex's Niagen) and also demonstrated efficacy. It argues "if the 'molecules are the same,' the Dellinger Study would apply equally to NIAGEN, rendering any 'first' or 'only' claim literally false." Dkt. No. 255 at 18–19. The existence of these two studies fails to create a genuine issue of fact. The Trammell Study does not support that Tru Niagen increases *and sustains* NAD+ levels. It demonstrated that the molecule Niagen administered at dosages of 100 mg, 300 mg, and 1000 mg on a one-time basis resulted in an increase in NAD+; it reported that Niagen administered at a dosage of 300 mg—the dosage in Tru Niagen—did not result in a statistically significant increase in NAD+ levels. Moreover, the

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opportunity to defend. It cannot simply assert it in opposition to the motion for summary judgment—to which its distinctions from the statements actually pled is significant—without having alleged it in an operative pleading. *See infra* note 19.

<sup>&</sup>lt;sup>10</sup> The same applies to Elysium's other "first" claims, including that "Basis was the world's first cellular health product informed by genomics," and that Basis was the "first product out there, available now, that comes out of basic rigorous research on aging. *See* Dkt. No. 222 at 16 n.4; Dkt. No. 255 at 18 n.8. There is no genuine dispute that Basis was the first such consumer product. ChromaDex points to no evidence of such a product that predated the introduction of Basis to the direct-to-consumer supplement market.

study tested only a one-time administration of Niagen, and thus did not demonstrate anything about Tru Niagen's ability to sustain NAD+ levels. As to the Dellinger Study, it did not study Tru Niagen. It tested the efficacy of Basis, a supplement that combines 250 mg of NR with PT. Tru Niagen has a completely different formulation, and does not contain PT. The fact that the Dellinger Study shows the effectiveness of Basis does not support that Tru Niagen is clinically proven effective.

Second, ChromaDex argues that the statement is false because Elysium continued making it after "numerous other clinical studies of NIAGEN that were as long as—if not longer—than Elysium's study," including the Conze Study. Dkt. No. 255 at 18–19. This argument has greater merit. The Conze Study<sup>11</sup> tested Niagen at 300 mg and showed that it increased NAD+ levels within two weeks and that such increase was sustained throughout the remainder of the eightweek trial. As such, if the Conze Study is credible, it follows that Basis is not the "only" supplement clinically proven to increase and sustain NAD+ levels; the Conze Study proved the same of Tru Niagen. Elysium, however, argues that it is entitled to summary judgment because "the Conze Study is unreliable because ChromaDex artificially depleted NAD+ levels through a restrictive diet in advance of the study." Dkt. No. 273 at 9. The parties discuss the evidence demonstrating the reliability—or unreliability—of the Conze Study at length in context of ChromaDex's motion for summary judgment on Elysium's Counterclaim. For the reasons discussed *infra*, the Court finds that there is a genuine issue as to the reliability of the Conze Study. If the jury were to resolve that disputed issue in favor of ChromaDex, there would be

<sup>&</sup>lt;sup>11</sup> The remainder of the studies ChromaDex points to tested Niagen at dosages significantly higher than the 300 mg dosage in Tru Niagen; the Martens Study tested Niagen at a 1000 mg per day dosage, and the Dollerup Study tested Niagen at a 2000 mg per day dosage. Dkt. No. 230, Ex. 5 at 9.

evidence from which it could find Elysium's statement to be false. As such, Elysium's motion for summary judgment as to this statement is denied.

# c. Statements Regarding Synergistic Effects of Combining NR with PT

Elysium argues that it is entitled to summary judgment on ChromaDex's claim that Elysium falsely stated that the NR and PT in Basis have a synergistic effect. Dkt. No. 222 at 15 (citing SAC ¶¶ 88–94). The Complaint alleges that "Elysium has repeatedly misrepresented that Basis is more effective than its competitors because its active ingredients NR and PT combine to produce a synergistic effect that is greater than their sum." SAC ¶ 88. It identifies two specific statements by Elysium—one on the website and the other in the *MIT Technology Review*:

- "[O]n its website, Elysium states that '[t]he proprietary formulation of nicotinamide riboside and pterostilbene is designed to increase levels of the coenzyme NAD+ and to support a class of proteins called sirtuins. NAD+ and sirtuins work together in vital cellular processes including energy production." SAC ¶ 91 (quoting Ex. W). 12
- "[I]n an interview with *MIT Technology Review*, published on February 3, 2015, Elysium co-founder Guarente discusses the presence of NR and PT in Basis and touts, '[w]e expect a synergistic effect [from] combining them." *Id.* ¶ 92 (quoting Ex. X).

Elysium argues that in fact it "never claimed that there is a proven synergistic effect between NR and PT." Dkt. No. 222 at 15. ChromaDex disputes this, arguing that "Elysium states that they have never advertised Basis as having an established synergistic effect, only an expected effect. This is not true." Dkt. No. 255 at 20 (citing Dkt. No. 257, Ex. 30).

Elysium is entitled to summary judgment. The statements on the Elysium website and to the *MIT Technology Review* do not claim that PT and NR have a synergistic effect. The website statement speaks to the "design" of Basis—that the formulation of NR and PT was designed to increase levels of NAD+. It does not speak to the effect of the combination of NR and PT or

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<sup>&</sup>lt;sup>12</sup> ChromaDex challenges only the portion of this statement claiming a synergistic effect between NR and PT, not the statement about how NAD+ and sirtuins work together.

whether the design was successful—a statement that could only be made after the product was designed and after there was a period for study of its results in operation which, as Elysium explained in one of the challenged communications, could take decades. Cf. In re Axonyx Securities Litig., 2009 WL 812244, at \*3 (S.D.N.Y. Mar. 27 2009) (holding that statements that trials were "intended to demonstrate the safety and efficacy" of a drug were "accurate on their face" despite allegations that the trials were in fact defective). A reasonable reader might take the implication from the fact that a retailer was advertising the design of its product that the retailer had determined such design was effective. But Elysium's communication does not necessarily or unambiguously convey that message. The more natural reading, and a reasonable reading, is that the combination of the two chemicals were "devise[d] for a specific function or end," see Merriam-Webster Online Dictionary, available at https://www.merriamwebster.com/dictionary/design (last updated Jan. 21, 2022), to operate in combination and that the scientists had a good-faith belief that they would do so. Because ChromaDex has not offered extrinsic evidence that a "statistically significant part of the commercial audience" took away the allegedly false belief, see Board-Tech, 737 F. App'x at 560, ChromaDex is not entitled to a jury trial on the issue.

ChromaDex's claim based on the statement to the *MIT Technology Review* suffers from the identical flaw. The statement, which was made before Basis was available at retail, reflected Elysium co-founder Guarente's expectation with respect to the combination of NR and PT. An expectation looks forward to a future event, *see* Merriam-Webster Online Dictionary, *available at* https://www.merriam-webster.com/dictionary/expecting (last updated Jan. 21, 2022); it is different than a current effect. The statement thus does not address the effect of the combination of the two ingredients. In fact, in the very same interview in which he stated that "[w]e expect a

synergistic effect from combining [NR and PT]," Guarante explained to the MIT Technology Review that "it's nearly impossible to prove, in any reasonable time frame, that drugs that extend the lifespan of animals can do the same in people; such an experiment could take decades." SAC, Ex. X. ChromaDex has not offered evidence that Guarante did not expect a synergistic effect. Guarante's statement in the interview that a synergistic effect between PT and NR was expected was neither literally false nor misleading; considered either in isolation or in context, it could not be reasonably interpreted to mean anything other than that Guarante believed the PT and NR would be synergistic. It did not convey that such an effect was proven or demonstrated. See Time Warner Cable, 497 F.3d at 158 ("[A] district court evaluating whether an advertisement is literally false 'must analyze the message conveyed in full context,' i.e., it 'must consider the advertisement in its entirety and not . . . engage in disputatious dissection." (first quoting Castrol Inc. v. Pennzoil Co., 987 F.2d 939, 946 (3d Cir. 1993); and then quoting Avis Rent A Car System, Inc. v. Hertz Corp., 782 F.2d 381, 385 (2d Cir. 1986))). Nor is there evidence that a statistically significant portion of the commercial audience took away a different understanding.

ChromaDex falls back on an internal Elysium email in which one Elysium employee states that in a communication with a news outlet Elysium should "harp on the fact that the synergistic effect of the combination is a huge benefit to consumers and a big differentiator," and another Elysium employee agrees. Dkt. No. 257, Ex. 30. The chain ends with the recommendation that Elysium put the message in one email to the news outlet. *Id.* ChromaDex offers no evidence that the message was ever delivered. As Elysium points out in its reply, Exhibit 30 contains "*draft* talking points in an *internal* e-mail," Dkt. No. 273 at 12. ChromaDex has not pointed to any evidence, in its briefing or its 56.1 statements, either that the talking points

were actually used or that Elysium ever claimed in any advertising or promotion that there is a proven or established synergistic effect between PT and NR; internal statements do not constitute "commercial advertising or promotion" and are not actionable under the Lanham Act. *See Fashion Boutique*, 314 F.3d at 57 ("[T]he touchstone of whether a defendant's actions may be considered 'commercial advertising or promotion' under the Lanham Act is that the contested representations are part of an organized campaign to penetrate the relevant market. Proof of widespread dissemination within the relevant industry is a normal concomitant of meeting this requirement."); *id.* at 58 (holding that evidence of "a total of twenty-seven oral statements regarding plaintiff's products in a marketplace of thousands of customers" is "insufficient to satisfy the requirement that representations be disseminated widely in order to constitute 'commercial advertising or promotion' under the Lanham Act").

### d. Statements Regarding FDA Regulation of Basis

ChromaDex next challenges certain of Elysium's statements relating to compliance with FDA regulations. Elysium made the following statements on its website:

- "We conduct rigorous safety studies for new dietary ingredient (NDI) submissions to the FDA. The Federal Food, Drug, and Cosmetic Act (FD&C) requires that we submit studies to demonstrate the safety of 'new dietary ingredients." SAC ¶ 63(c)(iv), Ex. K.
- Basis complies with "regulations as stipulated by the FDA." SAC, Ex. K.
- Basis "Exceeds FDA Recommendations." Dkt. No. 257, Ex. 32. 13

Elysium also included an "informational" article on its website that states: "If a supplement maker introduces a new ingredient to the market it's supposed to notify the FDA." Dkt. No. 255

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<sup>&</sup>lt;sup>13</sup> This statement is the heading for a paragraph that states: "The ingredients in Basis have been tested for safety and are produced in facilities that meet FDA requirements." Dkt. No. 257, Ex. 32.

at 19 (internal quotation marks omitted) (quoting SAC, Ex. J).<sup>14</sup> ChromaDex claims that the statements are literally false. It argues that the first sentence of the first statement is untrue because "Elysium admits that it has never made an NDI submission to the FDA." *Id.* at 19–20. It makes no other arguments.

Elysium argues that ChromaDex has failed to satisfy its burden to identify evidence that would support that any of these statements is untrue. Elysium identifies evidence that it did conduct rigorous safety studies for new dietary ingredient (NDI) submissions to the FDA. It notes that when it used NR supplied by ChromaDex for Basis, that ingredient did have NDI status. Dkt. No. 222 at 15 (citing Joint 56.1 at 17–18). It points to the declaration of its Chief Product Officer that after it "began manufacturing its own NR, it initially planned to submit an NDI notification," and that it only later transitioned to seek IND status in 2018. Dkt. No. 222 at 15 (citing Morris Decl., Dkt. No. 227 ¶¶ 14–21). An IND application seeks approval to conduct clinical trials on a drug to be used for a specific medical treatment while an NDI which is a general notification required for new dietary ingredients in supplements. See 21 C.F.R. § 312.20(a); 21 U.S.C. § 350b(d). There is no evidence that the transition was made as a result of any difficulty with the NDI application or concerns that the product would not pass the safety studies. NDIs and INDs require similar levels of scientific rigor in proving safety. Dkt. No. 222 at 16 (citing Dkt. No. 223, Ex. Z at 33–34 ("If you're asking about the rigor, I would say that the scientific rigor around safety is comparable between these two approaches.")). Rather, although "[i]nitially, Elysium intended to submit an NDI for Basis," after studies positively evaluated the safety of Basis in patients with acute kidney injury, the company submitted an Investigational

<sup>&</sup>lt;sup>14</sup> ChromaDex's opposition cites Exhibit J; the challenged statement, however, appears in Exhibit L to the Second Amended Complaint.

New Drug (IND) application instead, which was accepted by the FDA, and subsequently decided not to pursue the NDI notification as well. Morris Decl. ¶¶ 16–21. Elysium further points out that its "reference to an NDI was removed after it decided to apply for IND status instead." Dkt. No. 273 at 11 (citing Dkt. No. 213, Ex. Y ¶¶ 10, 12).

ChromaDex does not point to any evidence that could support a finding that Elysium, at the time of the statements at issue, was *not* working on studies for an NDI notification. That fact is undisputed for purposes of this motion. Instead, it argues that Elysium failed to submit an NDI notification. But the statement at issue refers to the studies that Elysium was conducting and not to the applications it had made.<sup>15</sup> It does not necessarily or unambiguously convey that Elysium had submitted an NDI notification to the FDA. Indeed, no reasonable reader could come away with that conclusion. Accordingly, the evidence that Elysium later did not make an application to the FDA does not render the statement that Elysium did make literally false and creates no issue for trial. Elysium is entitled to summary judgment on this claim.

### e. Statement Regarding Elysium's Role in NR Research

Next, ChromaDex alleges that Elysium made statements that falsely implied that it was significantly involved with the research behind the ingredients in Basis. ChromaDex challenges:

- Statements on Elysium's website that Basis is "[t]he culmination of more than 25 years of aging research," that "Elysium turns critical scientific advancements in aging research into health solutions you can access today," and the websites direction to consumers to "take a tour of the science and history that led to Basis." Dkt. No. 222 at 17 n.5 (quoting SAC ¶ 63(b)(ii), Exs. D, G).
- Elysium's statement in an *Allure* article published on October 18, 2017 that "[w]ith regard to Basis, the pill seems simple, but the amount of research behind it is quite extensive." *Id.* (quoting SAC ¶ 63(b)(iii), Ex. H).

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<sup>&</sup>lt;sup>15</sup> At oral argument, counsel for ChromaDex referenced an "advertisement that says [Elysium has] submitted an NDI," which they stated was "either Exhibit D to the complaint or Exhibit DD to the complaint." Oral Argument Tr. at 98–99. Neither Exhibit D nor Exhibit DD to the operative complaint include such a statement. Complaint, Exs. D, DD.

ChromaDex argues that "[t]he reality is that neither Elysium nor any of its employees had done any research into NR before launching Basis." Dkt. No. 255 at 17. These are the only statements for which ChromaDex offers evidence of implied falsity. It offers the report of Bruce Isaacson, ChromaDex's survey expert, who ChromaDex retained to test how consumers viewed several of Elysium's statements. Isaacson tested a statement made on Facebook that "[i]nside this bottle is 25 years of research," and found that of respondents who viewed that statement "82.7% answered that the materials communicate or imply that the company conducted 25 years of research on aging, compared with 43.8% for the control." Dkt. No. 213-37 at 12–13. The control statement tested was: "Inside this bottle is years of research, that was conducted by us and others." *Id.* at 10.

Elysium makes two arguments for judgment in its favor. First, it claims that the Isaacson report is not admissible and that, in the absence of the Isaacson report, there is no evidence of implied falsity. Second, it argues that the statements imply at most direct involvement by Elysium in the research behind Basis and in research into *aging* and not in the research behind NR per se. Thus, even if these statements implied direct involvement by Elysium in the research behind Basis or into aging, that implication would be true because "[o]ver the course of 30 years of research, Guarente demonstrated the connection between aging and sirtuins, and then demonstrated the connection between sirtuins and NAD+." Dkt. No. 222 at 17.

The material facts are not disputed—Guarante did substantial research into NAD+ and aging. He has been the director of The Paul F. Glenn Center for Biology of Aging Research at MIT since 2008, Dkt. No. 256 ¶ 4, and "[i]n the three decades that [he] has operated a laboratory at MIT, [his] research has been focused on the genetic and molecular basis of aging," Dkt. No.

217 ¶ 5.¹6 Brenner testified at deposition that Guarente "has made seminal contributions to gene regulation and other aspects of molecular biology over the decades," and has done research on aging. Dkt. No. 223, Ex. 1 at 26–27. Guarente's research involved, among other things, research into the role of sirtuins in cellular aging, and the relationship between sirtuins and NAD+, which Basis is designed to boost—a study published by Guarente in 2000 demonstrated that NAD is necessary for yeast SIR2 activity. Dkt. No. 221 ¶¶ 7–9; Dkt. No. 256 ¶¶ 7–9. However, while he may have played an instrumental role in the research into NAD+ and how it affected aging, he was not involved in the research regarding the connection NAD+ and NR.

As an initial matter, the challenged statements do not either expressly or by necessary implication state that Elysium itself was involved with all of the research behind Basis, much less that it was involved in the research regarding NR; as such, they are not literally false. Fairly read, they make the point that Elysium's *product* is the result of more than twenty-five years of aging research and that Elysium's role is to convert or "turn" that research into a product not to conduct that research itself. They do not speak to the role of Elysium itself or its officers in the underlying research itself. It thus would be irrelevant to the truth or falsity of the statement, literally read, whether Elysium itself conducted any of the research either into aging or into NR. Elysium's statement would be literally true even if it piggybacked on the research done by others.

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<sup>&</sup>lt;sup>16</sup> ChromaDex challenges the validity of Guarente's declaration, Dkt. No. 256 ¶¶ 2–3, but fails to point to any evidence calling into question Guarente's history of research into aging. It cites Brenner's testimony that "Dr. Guarente has done very important work in yeast aging, which I believe is greatly overinterpreted." Dkt. No. 257, Ex. 1 at 29. Brenner agreed, however, that "research on aging and yeast can potentially tell us something about human aging," and that he has conducted experimentation on aging in yeast which has informed further experimentation in humans. *Id.* at 29–30. That testimony does not contradict Guarente's testimony that he did research into the role of sirtuins in the aging process, and the connection between NAD+ and sirtuins, both of which relate directly to the science behind Basis.

ChromaDex also has not identified any evidence to support a jury verdict that the statements were misleading or impliedly false. It relies on Isaacson's expert report, but, as stated, that report tested the statement "[i]nside this bottle is 25 years of research," and found that 82.7% of respondents thought the statement communicated or implied that "the company conducted 25 years of research on aging, compared with 43.8% for the control." Dkt. No. 213-37 at 12–13. The study thus supports the proposition that a net 38.9% of the commercial audience would understand Elysium's statement to imply that it had done the research—but only research on aging. ChromaDex has not identified any evidence to contradict the assertion that Elysium (or its founder) conducted twenty-five years of research on aging and that such research contributed to Basis. Thus, the evidence to which ChromaDex points that "neither Elysium nor any of its employees had done any research into NR before launching Basis," Dkt. No. 255 at 17, is insufficient to create a genuine issue of material fact whether the statement about research into aging is false. See Anderson v. Hertz Corp., 507 F. Supp. 2d 320, 326 (S.D.N.Y. 2007) ("A fact is 'material' when it 'might affect the outcome of the suit under the governing law.'" (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986))).

ChromaDex also argues that another challenged statement by Elysium regarding Elysium's involvement in research was literally false:

• Elysium's statement on social media that "Basis is revolutionary because it's the first product to come out of really good aging research." *Id.* (quoting SAC  $\P$  63(b)(iv), Ex. I).

ChromaDex argues that this statement is "demonstrably false," because (i) Basis combined two existing active ingredients, (ii) there were already multiple products on the market containing either NR or PT, and (iii) Elysium did not conduct its own research into either of these ingredients. Dkt. No. 255 at 18. Elysium responds that the statement that "Basis is revolutionary" is inactionable puffery, and ChromaDex does not proffer any evidence suggesting

that there were other products that combined NR and PT at the time the statement was made.

Dkt. No. 273 at 10.<sup>17</sup>

The statement that "Basis is revolutionary" is inactionable puffery. At worst, it reflects "an exaggeration or overstatement expressed in broad, vague, and commendatory language."

Time Warner Cable, 497 F.3d at 159 (quoting Castrol, 987 F.2d at 945); see also Lipton v.

Nature Co., 71 F. 3d 464 (2d Cir. 1995) (quoting Groden v. Random House, Inc., 1994 WL

455555, at \*5 (S.D.N.Y. Aug. 23, 1994), aff'd, 61 F.3d 1045 (2d Cir. 1995), for the statement that "[s]ubjective claims about products, which cannot be proven either true or false, are not actionable under the Lanham Act," and concluding accordingly that a party's "general assertion that the research he conducted was 'thorough[]' is mere 'puffing' and therefore, not actionable").

"Such sales talk, or puffing, as it is commonly called, is considered to be offered and understood as an expression of the seller's opinion only, which is to be discounted as such by the buyer. . . .

The 'puffing' rule amounts to a seller's privilege to lie his head off, so long as he says nothing specific." Time Warner Cable, 497 F.3d at 159 (internal quotation marks omitted) (quoting Castrol, 987 F.2d at 945 (quoting W. Page Keeton et al., Prosser and Keeton on the Law of Torts § 109, at 756–57 (5th ed. 1984))).

<sup>&</sup>lt;sup>17</sup> ChromaDex's complaint also alleged that "Elysium falsely claims to be the 'first' to market." SAC ¶ 12. Elysium's motion for summary judgment argues that it "never made that claim," and that even if it did, such a statement would not be false because "Elysium was the first to sell NR and PT in combination as a single product and ChromaDex did not enter the direct-to-consumer market until after Elysium." Dkt. No. 222 at 16. ChromaDex's opposition does not respond to these arguments or defend the allegations that Elysium claimed to be the 'first' to market and that this statement was false. Therefore, the Court deems this allegation abandoned, and examines only the specific "first" and "only" claims that ChromaDex defends in its memorandum. *See* Dkt. No. 255 at 18−19; *see also, e.g., Shenk v. Karmazin*, 868 F. Supp. 2d 299, 311 n.12 (S.D.N.Y. 2012); *Taylor v. City of New York*, 269 F. Supp. 2d 68, 75 (E.D.N.Y. 2003); *Douglas v. Victor Capital Group*, 21 F. Supp. 2d 379, 393 (S.D.N.Y. 1998).

The claim that a product is "revolutionary" is broad and vague and cannot "be proven either true or false." *Lipton*, 71 F.3d at 474. It is not "specific and measurable." *Castrol*, 987 F.2d at 946. No one would understand it to be making a verifiable claim of fact regarding Elysium's "goods, services, or commercial activities" or those of another person. 15 U.S.C. § 1125(a)(1)(B). It therefore is not independently actionable.

Elysium's claim that Basis is "the first product to come out of really good aging research" is more concrete and measurable in the sense that it conveys that it was the "first" product to come out of the aging research and that there were not others that preceded it.

However, ChromaDex has not pointed to evidence that would support a finding that Elysium's statement was false. Although ChromaDex claims that "there is no dispute that . . . there were already numerous NIAGEN-containing products and numerous pterostilbene-containing products on the market when Basis launched in 2015," Dkt. No. 255 at 18, it cites to no evidence supporting that claim or indicating what products it refers to. While ChromaDex manufactured Niagen and pTeroPure before Elysium launched Basis, those were wholesale ingredients and not consumer products. As such, the record does not reflect any genuine dispute of material fact as to whether Basis was the first product of its kind to come out of the aging research in question.

## f. Statement that Elysium is the Exclusive Licensee of a NR Patent

ChromaDex's Complaint alleges that "Elysium falsely represents to consumers that it is the exclusive licensee of a patent for the use of NR for the slowing of aging." SAC ¶ 63(e). The challenged statement, contained in a press release issued on August 16, 2018, is:

Elysium Health Inc.,<sup>TM</sup> a life sciences company developing clinically validated health products based on aging research, has entered into an exclusive license agreement with Mayo Clinic and Harvard University to use nicotinamide riboside for dietary supplement applications in the slowing of aging and age-related diseases. . . . "With this license . . . we are excited to build upon Elysium Health's intellectual property portfolio to support our leading research in the field of aging."

*Id.* ¶ 63(e)(ii) (quoting Ex. O). ChromaDex alleges that this announcement "is intended to make consumers believe that Elysium is the exclusive licensee of a patent obtained by Harvard and the Mayo Clinic and is now the only party that can sell NR supplements for use in connection with aging or age-related diseases." *Id.* It states "[i]n reality, Elysium has licensed a patent application—not an issued patent." *Id.* ¶ 63(e)(iii)—(iv).

The Court "must analyze the message conveyed in full context." *Time Warner Cable*, 497 F.3d at 158 (quoting *Castrol*, 987 F.2d at 946). In full context, the press release does not state or convey that Elysium is the exclusive licensee of an issued patent for NR. It states that Elysium has an exclusive license agreement with two institutions—Harvard and the Mayo Clinic—for the purpose of using NR for dietary supplement applications. The first reference to a patent is in the third paragraph and it refers to a "pending patent" for a specific pathway to increasing NAD+ (i.e., a patent application)—one involving a crucial enzymatic system, the CD38 pathway, was the main regulator of intracellular NAD+ levels and sirtuin 1 in living organisms. Dkt. No. 139, Ex. O. The statement, therefore, when "considered in context," does not "necessarily and unambiguously imply a false message," and as such is not literally false. *Church & Dwight*, 843 F.3d at 65 (quoting *Time Warner Cable*, 497 F.3d at 158).

Elysium further argues that there is no evidence that consumers took away a misleading message from the release. ChromaDex, in its opposition, does not address this claim at all, let alone point to extrinsic evidence suggesting that the press release is misleading.

#### g. Statements Regarding the Amount of NR in Basis

Next to last, ChromaDex alleges that Elysium made statements about the amount of NR in Basis, and that these statements were false. "Elysium advertises that a dose of Basis contains 250 mg of NR." SAC ¶ 95. In its complaint, ChromaDex alleged "testing of commercially

available Basis revealed that as many as a third of Basis doses sold to consumers contain materially less NR." *Id.* (internal citations omitted).

Elysium argues that it is entitled to summary judgment on this claim. The challenged statement is a response to one of a set of Common Questions on Elysium's website. Dkt. No. 139, Ex. G. The question is, "What are the ingredients in Basis?" The answer is, "Each serving of Basis (two capsules) contains 250mg of Elysium's crystalline nicotinamide riboside and 50mg of pterostilbene. See nutrition label for a full list of ingredients." *Id.* The Common Questions page goes on to state that Elysium "recommend[s] two capsules in the morning, with or without food." *Id.* The statement is literally true. Elysium has identified evidence from discovery that Basis "is tested by third parties that verify the dosage of ingredients meets or exceeds the dosage claimed by Elysium." Dkt. No. 222 at 18 (citing Morris Decl., Ex. B). Exhibit B to the Morris Declaration, the evidence to which Elysium cites, reflects that of all the tested batches, the amount of NR in a capsule exceeded the label claim of 125 mg of NR; results ranged from 126 mg to 149 mg. Dkt. No. 227-2. ChromaDex identifies no evidence that Elysium's statement is false. Elysium is entitled to summary judgment on this claim.

## h. Statements Regarding the Scientific Advisory Board and Client Testimonials

Finally, ChromaDex claims that Elysium's statements regarding its Scientific Advisory Board and Client Testimonials are misleading to consumers. SAC ¶¶ 64–74.

## i. Scientific Advisory Board

Elysium states that it "works in partnership with the world's leading scientists and research universities," and that their "board guides the scientific direction of Elysium." *Id.* (quoting Exs. P, Q).

ChromaDex's Complaint does not allege that any of the statements Elysium makes about the board are literally false. The SAB "holds formal quarterly meetings with Elysium's team, and members otherwise interact regularly and meet on an ad hoc basis with Elysium team members. During the quarterly meetings, Elysium's team presents on current and planned products, ongoing clinical trials and new data. SAB members ask questions, give input and generally advise Elysium on pursuing research, designing clinical studies and translating that work into accessible products. Certain members of the SAB have also conducted studies or testing using Basis." Dkt. No. 225 ¶ 6 (declaration of Dan Alminana, Elysium's Chief Operating Officer).

Rather, ChromaDex argues that even if it is true that Elysium has an active SAB, the statements leave the misleading impression that the SAB "guides the scientific direction of Elysium," SAC ¶ 65 (quoting Ex. Q), and "give[s] consumers the false impression that these scientists were involved in the science and discovery behind the Basis product, were active in research and development at Elysium, and can vouch for Basis' safety and efficacy," *id.* ¶ 64. ChromaDex says that such statements would be untrue because the SAB scientists were not involved in the science and discovery behind the Basis product, were not active in research and development, and could not vouch for Basis's safety and efficacy. According to ChromaDex, "Elysium largely ignored its scientific advisory board, using them for nothing more than the veneer of credibility." Dkt. No. 255 at 20 (citing Dkt. No. 255 at II.D.3.C).

Elysium's statements do not either expressly state or necessarily and unambiguously imply that its SAB—which is claimed to be an *advisory* board—was itself involved in the research and development or would vouch for Basis's safety and efficacy. It is plausible that a reader might take away that message from the statement. But it is equally plausible that

Elysium's scientists and executives use the SAB as an "advisory" board—to obtain advice and opinions from it without requiring of its members that they become active in research and development and without requiring of itself that it blindly accept any opinion of a member of the SAB, without making its own independent judgment regarding safety and efficacy. See Apotex, 823 F.3d at 67 (holding that "plausible" understanding of a statement does not make it literally false when it is not "unambiguous"). It is a positive thing for a company to appoint an advisory board or to obtain advisors and to inform the public that it has done so. Absent a false statement about what the advisory board has done or the capacity in which its members serve, a company is not required to convert every advisor to an officer or to follow each piece of advice it receives at the expense—if it does not do so—of inviting a Lanham Act lawsuit. Moreover, ChromaDex has not identified evidence that "a statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement." See Board-Tech, 737 F. App'x at 560 (internal alterations omitted) (quoting *Tiffany*, 600 F.3d at 112–13)); *Time* Warner Cable, 497 F.3d at 153 ("[A] district court must rely on extrinsic evidence to support a finding of an implicitly false message." (internal alterations and citations omitted)); Board-Tech, 737 F. App'x at 560–61 (citing *Time Warner Cable* for the same proposition). Isaacson's expert report, ChromaDex's only extrinsic evidence relating to consumer impressions from Elysium's advertising, did not test consumer impressions of any statements relating to Elysium's Scientific Advisory Board. See Dkt. No. 213-17.

In any event, ChromaDex fails to support its broad claim that Elysium largely ignored its scientific advisory board or used it as nothing more than a "veneer" and fails to raise a genuine issue of material fact for trial. ChromaDex claims that "Elysium's scientific advisory board recommended eliminating PT from Basis because 'a 10% increase in cholesterol is not trivial,"

and that there "was Board consensus that, at the very least, additional studies were needed" but "Elysium has not published any follow-up studies on the effect of either PT or the NRPT combination on LDL levels." Dkt. No. 255 at 12 (citing Dkt. No. 257-24). The Court has addressed this claim earlier in its opinion. The evidence ChromaDex cites does not support its argument or create a triable issue. The statement that "a 10% increase in cholesterol is not trivial" was not a recommendation by the board; it was contained in an email from a board member who missed the meeting to other board members and included the caveats that he was expressing his "personal opinion[n]" and that "I may misunderstand some of the results or facts." Dkt. No. 257-24 at 2. The email adds: "I am really impressed by the effect of BASIS on NAD levels, blood pressure, and transaminases" and that it is "possible that the effect on LDL cholesterol is transient." Even construing the evidence favorably to ChromaDex, the study about which he was writing—the Dellinger Study—did not show a 10% increase in cholesterol in the recommended dosage. See Dkt. No. 257-4 at 159-60. It showed an increase in a dosage that was not recommended. The Scientific Advisory Board's recommendation was not that Elysium should eliminate PT from Basis, but rather that Elysium should conduct a follow-up study; Elysium did so. It conducted a follow-up study which tracked the effects of Basis on cholesterol levels over time, as recommended by the Scientific Advisory Board. See Dkt. No. 257, Ex. 4 at 168–71. Guarente testified that the study "did not show a significant effect of Basis on LDL cholesterol." *Id.* at 171. Thus, even if the statement that the Scientific Advisory Board "guides the scientific direction of Elysium" was concrete enough to be susceptible to a challenge of literal falsity and gave rise to the messages ChromaDex claims it conveyed, ChromaDex has not identified evidence that such message was false.

#### ii. Client Testimonials

Elysium showcases client testimonials on its website, including:

- A testimonial from customer Pamela Olin, who is quoted as saying, "I liked the fact that Elysium has scientists on staff. I liked the fact that there is data . . . . It just seemed like two simple ingredients. The fact that there are so many knowledgeable people involved in this, and that you were so responsive when I had questions. It left me feeling secure in the knowledge that I was given and made it worth a shot. I'm thoroughly enjoying it." SAC ¶ 72 (quoting Ex. R) (emphasis added by ChromaDex in the SAC).
- A testimonial from customer Suzy Oo, who is quoted as saying, "I was following Dr. Guarente's work actually. Scientists have their groupies—I guess I was one of his. He's kind of a rockstar in the scientific community . . . I went through the original research papers. I looked at it as a hypothesis. Based on what's out there, is it likely to work and is it going to cause me any harm? Based on everything I read I didn't think it was going to cause me any harm, and based on the literature I thought Basis made sense." *Id.* ¶ 73 (quoting Ex. S).
- A testimonial from customer Tom Flynn, who is quoted as saying, "I came across an article about Elysium. I said, let me look at this because of the credibility of the founder and his work at MIT. I was buoyed by the idea that these people had confidence in the research and were promoting it." *Id.* ¶ 74 (quoting Ex. T).

ChromaDex does not allege in its Complaint that these testimonials are literally false.

Rather, it alleges only that "Elysium compounds its deceptive information by including client testimonials, emphasizing their reliance on the alleged scientific foundation of Basis, and their comfort level afforded by Elysium's bevy of apparent sponsors from medical and scientific fields." *Id.* ¶ 71. ChromaDex proffers no evidence that these client testimonials were fabricated, mislead consumers, or conveyed an implied message to consumers that was false; this evidentiary defect is fatal to its claim. Moreover, "a collection of client reviews reflects subjective judgments. A reasonable reader would understand that each review is merely an opinion." *Davis v. Avvo, Inc.*, 345 F. Supp. 3d 534, 543 (S.D.N.Y. 2018) "Not only are the positive reviews opinions, but simply indicating that a particular consumer was satisfied with a service plainly does not constitute a false or misleading statement." *Id.* Finally, although Elysium makes this argument in its motion for summary judgment, ChromaDex does not defend its allegations in its opposition and does not address the client testimonials at all. As such, these allegations are deemed abandoned. *See, e.g., Shenk v. Karmazin*, 868 F. Supp. 2d 299, 311 n.12

(S.D.N.Y. 2012); *Taylor v. City of New York*, 269 F. Supp. 2d 68, 75 (E.D.N.Y. 2003); *Douglas v. Victor Capital Group*, 21 F. Supp. 2d 379, 393 (S.D.N.Y. 1998).

### 2. Elysium's Counterclaims

ChromaDex's motion for summary judgment on Elysium's counterclaims as to the falsity element of the Lanham Act is granted in part and denied in part. ChromaDex's motion is granted with regard to Elysium's counterclaims about statements regarding ChromaDex's funding and scientific research, statements that Niagen increases NAD+ levels by 60%, statements about the safety and trustworthiness of Tru Niagen, and statements about FDA regulation of ChromaDex's products that make no explicit mention of efficacy. ChromaDex's motion is denied with regard to statements that Brenner discovered NR, statements that Tru Niagen increases NAD+ levels by 40–50%, statements about "other NAD-dependent clinical study results," statements about FDA regulation of ChromaDex's products that do explicitly mention efficacy, and statements that ChromaDex is the only seller of NR.

Elysium's motion for partial summary judgment on its own counterclaims is granted with regard to the statement on the Counterfeit Page that ChromaDex is the only seller of NR, but denied with regard to the messages on that page that Basis is inauthentic, unsafe, and ineffective.

### a. Statements Regarding ChromaDex's Role in Research

Elysium's counterclaims challenge various categories of ChromaDex's statements about their role in the research and development of NR.

#### i. Brenner Discovered NR

First, Elysium alleges that ChromaDex's website "touts . . . [t]he false assertion that ChromaDex's lead scientist discovered NR in 2004, even though NR was discovered more than 50 years ago." Counterclaim ¶ 84. ChromaDex made the following challenged statements:

- On the "FAQ" page of the Tru Niagen website, it stated that "[i]n 2004, Charles Brenner PhD discovered a unique and overlooked form of vitamin B3 (nicotinamide riboside) that is a natural precursor to NAD." *Id.* ¶ 85 (quoting Ex. 4).
- On the "Our Product" page of the Tru Niagen website, addressing another FAQ how Tru Niagen is "different from other vitamin B3," ChromaDex answers that "Tru Niagen is a specialized form of vitamin B3 *discovered by our Chief Scientific Advisor Charles Brenner, PhD* and developed specifically to increase NAD more effectively than any other B3 before it." *Id.* ¶ 86 (emphasis in original) (quoting Ex. 5).

The first of these statements is on a page on the Tru Niagen website with several other FAQs. The second of these statements—which appears on the Product page of the Tru Niagen website—is in one of the two FAQs included on that page, underneath which there is a link to "SEE ALL FAQS." Counterclaim, Ex. 5 at 4. That link brings the viewer to the FAQ page, on which many FAQs appear—including the first of these statements.

ChromaDex does not dispute that if the statements asserted that Brenner discovered NR, they would be false. Brenner did not discover NR, which was identified in the 1940s. There is evidence he discovered a use for NR and a method to make synthetic NR. Rather, ChromaDex argues that the statements cannot be read to advertise that Brenner discovered NR. With regard to the first challenged statement—the statement on the FAQ page that Brenner "discovered a unique and overlooked form of vitamin B3 (nicotinamide riboside)"—it argues that "[s]tatements are to be read in context." Dkt. No. 210 at 11 (quoting *Reed Const. Data Inc. v. McGraw-Hill Companies, Inc.*, 49 F. Supp. 385, 411 (S.D.N.Y. 2014), *aff'd*, 638 F. App'x 43 (2d Cir. 2016)). It points to an additional statement on that same FAQ page that, it asserts, provides context to the challenged statement:

• The statement on the FAQ page, addressing "How Much Research Has Been Done On NIAGEN®?" that "[a] naturally-occurring, unique form of vitamin B3 known as nicotinamide riboside was first identified in the 1940s. This discovery came years after it was established that vitamin B3, in the common forms of niacin and niacinamide, could cure a disease caused by vitamin B3 deficiency known as pellagra. Since that time, the role of nicotinamide riboside as a precursor to an essential coenzyme called NAD has been widely studied in the scientific community and become better understood." Dkt. No. 210 at 11–12 (emphasis in original) (quoting Counterclaim, Ex. 4).

ChromaDex argues that "looking at the full context, the at-issue page clearly states that naturally-occurring nicotinamide riboside was first identified in the 1940s." *Id.* at 12. It reasons that, in context, the first statement that in 2004, Brenner discovered a "unique and overlooked form of vitamin B3 (nicotinamide riboside)" could not be read to refer to the earlier-discovered NR. *Id.* 

It is true that "a district court evaluating whether an advertisement is literally false 'must analyze the message conveyed in full context,' i.e., it 'must consider the advertisement in its entirety and not . . . engage in disputatious dissection.'" *Time Warner Cable*, 497 F.3d at 158 (first quoting *Castrol*, 987 F.2d at 946; and then quoting *Avis Rent A Car*, 782 F.2d at 385). But the FAQs as a whole do not qualify or dispel the notion that Brenner was the one who discovered NR and that he did so in 2004.<sup>18</sup>

<sup>&</sup>lt;sup>18</sup> Elysium makes a separate argument that is not meritorious. Relying on *Mantikas v. Kellogg Co.*, 910 F.3d 633, 637 (2d Cir. 2018), it argues that "a consumer should not be expected to go searching for the truth; it's up to the advertiser to make it clear in the context that's immediately available to the consumer," Oral Argument Tr. at 38–39; Dkt. No. 250 at 21 (same). The argument is based on the supposition that a reader of the first statement would have to expand the FAQs to view the purportedly clarifying statement. In *Kellogg*, the Second Circuit held that representations in the center of the front of a Cheez-It box that product was "WHOLE GRAIN" was not qualified by "Nutrition Facts" on the side of the box, which said in smaller print that the serving size was twenty-nine grams and that the first ingredient in the product was "enriched white flour," because "a reasonable consumer should not be expected to consult the Nutrition Facts panel on the side of the box to correct misleading information set forth in large bold type on the front of the box." 910 F.3d at 634–35. But the first challenged statement—the one at issue here—appears (on the record before the Court) only on the FAQ page, in the third paragraph of the answer to the sixth FAQ. Counterclaim, Ex. 4 at 2. The statement that ChromaDex asserts clarifies that NR was first identified in 1940 appears in the first paragraph of

The statement that "Charles Brenner PhD discovered a unique and overlooked form of vitamin B3 (nicotinamide riboside) that is a natural precursor to NAD" means, unambiguously and in plain English, that Brenner discovered *NR*, which is a natural precursor to NAD, not that he discovered that NR is a natural precursor to NAD. The "context" of the additional statement that "nicotinamide riboside was first identified in the 1940s" does not clarify what the earlier statement meant and thus render it in fact true as properly understood; it contradicts the earlier statement on its face and, if credited, reveals that the earlier statement is false. This claim thus survives summary judgment.

ChromaDex's argument with respect to the second statement is no more successful.

Conceding again that Brenner was not the discoverer of NR, it argues that there is ambiguity in the statement that "Tru Niagen is a specialized form of vitamin B3 discovered by our Chief Scientific Advisor Charles Brenner, PhD," in that the statement can refer to the discovery of Niagen or Tru Niagen and not to the discovery of NR. <sup>19</sup> But for a statement to be ambiguous,

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the answer to the eighth FAQ on the same page. The protracted "investigation process," Oral Argument Tr. at 39, that Elysium describes simply does not exist.

<sup>&</sup>lt;sup>19</sup> Elysium, in response, points to additional statements by ChromaDex that clearly states that Brenner discovered NR, including the statement on the "Science" page of the Tru Niagen website that "in 2014, Dr. Brenner discovered a naturally occurring vitamin in milk called nicotinamide riboside," Dkt. No. 250 at 21 (quoting Dkt. No. 245, Ex. AAA), and the headline of a Facebook advertisement for an interview with Brenner which says: "Listen: The Scientist Who Discovered Nicotinamide Riboside Talks about NAD & Staying Healthy As We Age," id. (quoting Dkt. No. 245, Ex. BBB). These statements are raised for the first time in Elysium's opposition to ChromaDex's motion for summary judgment; they are not referenced in Elysium's Counterclaim. The Court thus does not consider them here for the purposes of determining whether the challenged advertising is literally false. Although "false advertising causes of action under the Lanham Act are generally framed in terms of claims (i.e., messages or statements) that are embodied in advertising, rather than each specific piece of advertising containing that claim," Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics GmbH, 2014 WL 5769236 (S.D.N.Y. Oct. 28, 2014), that principle means that a court can enjoin and a plaintiff can recover for advertising beyond what is listed in the complaint when it contains the same defect as the advertising in the complaint, see id. (citing Am. Home Prods. Corp. v. Johnson & Johnson, 577 F.2d 160, 160 (2d Cir. 1978), for its affirmance of an "injunction that prohibited 'any

requiring extrinsic evidence of meaning, there must be more than one reasonable reading of the statement. *See Time Warner Cable*, 497 F.3d at 158 ("[I]f the language or graphic is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false."). There is not more than one reasonable interpretation here. The statement refers plainly and unambiguously to NR. It cannot be reasonably read to refer to synthetic NR or Niagen or to ChromaDex's product Tru Niagen. Neither is "a specialized form of vitamin B3"—they are products and not molecules; nor could any reader understand the statement to mean that Brenner discovered Niagen or Tru Niagen and not NR. Niagen and Tru Niagen are not things that can be "discovered"; they are a wholesale product and a dietary supplement created by ChromaDex.

Nor could Brenner have "discovered" synthetic NR. To "discover" means "to make known or visible," "to obtain sight or knowledge of for the first time," or to "find out." Merriam-Webster Online Dictionary, *available at* https://www.merriam-webster.com/dictionary/discover (last updated Jan. 23, 2022). It thus entails uncovering something that *already existed*. The parties spend a lot of time arguing about whether synthetic

advertisement or promotional material which contains' the false or misleading message about that product' and Santana Prods v. Bobrick Washroom Equip., Inc., 249 F. Supp. 2d 463, 522–23 (E.D. Pa. 2003), rev'd on other grounds, 401 F.3d 123 (3d Cir. 2005), for its rejection of an argument . . . that a false advertising plaintiff "cannot seek recovery for any advertisement beyond those listed in the complaint' because "all of [defendants] advertising materials suffer from the same defect raised in the original complaint' (emphasis added)). Here, considering these statements that were not raised in the Counterclaim to determine whether the challenged advertising is literally false would aid Elysium only if the statements alleged in its Counterclaim were not literally false but the newly raised statements were. In that case, the newly raised statements are not merely additional examples of the same, defective advertising claim raised in the Counterclaim; they are materially different statements that could be the basis of an actionable Lanham Act Claim while the claims raised in the Counterclaim are not. As such, these statements may be relevant to the scope of relief if judgment on liability is rendered in favor of ChromaDex, but the Court does not consider these statements at this stage.

NR differs from the NR that appears in nature<sup>20</sup>; ultimately, however, the answer is immaterial. Synthetic NR is either something that Brenner *created* for the first time and which did not exist prior to that—and therefore is not something that can be "discovered"—or synthetic NR is something that existed in nature—that is, NR itself, which Brenner did not discover and was in fact discovered in the 1940s. Because a reading of ChromaDex's statement as conveying that Brenner discovered synthetic NR is either an implausible reading, because synthetic NR differs from the NR in nature and did not exist prior to Brenner's development of it and therefore could not be "discovered," or is literally false, because synthetic NR is the same as the NR which exists in nature, which was discovered in the 1940s, the dispute over whether synthetic NR is the same as the NR in nature is not a genuine dispute as to a *material* fact.

The statement that "Tru Niagen is a specialized form of vitamin B3 discovered by our Chief Scientific Advisor Charles Brenner, PhD," thus necessarily implies that Brenner discovered "a specialized form of vitamin B3"—i.e., NR, the "specialized form" of B<sub>3</sub> at issue. Cf. Counterclaim, Ex. 4 (describing "[a] naturally-occurring, unique form of vitamin B3 known as nicotinamide riboside"). ChromaDex, as the summary judgment movant, fails to demonstrate

<sup>&</sup>lt;sup>20</sup> Elysium argues that "synthetically produced nicotinamide riboside in Tru Niagen is identical to naturally occurring nicotinamide riboside in any event." Dkt. No. 250 at 21 (citing Dkt. No. 251, Ex. PP at 51–52 (Kruger deposition transcript, in which she agrees that the NR molecule is the same in Niagen and in nature, but some of the byproducts and the impurity profile may be different); Dkt. No. 251, Ex. TT at 83–86 (Jaksch deposition transcript, in which he confirms that the NR in Tru Niagen "is structurally and functionally identical to naturally-occurring NR"); Dkt. No. 245, Ex. CCC (screenshot of the Tru Niagen website stating that the NR in Tru Niagen is "nature-identical" because "[t]here is no structural or chemical difference between the two"). ChromaDex disputes this, arguing that "the record is clear that naturally occurring NR is not the same as synthetic, isolated NR." Dkt. No. 262 at 6. To support this, ChromaDex points only to the same portion of the Kruger deposition as Elysium does. Kruger's testimony is that there is no difference between natural NR and the NR in Niagen, but that the Niagen product contains byproducts and impurities that natural NR does not.

that the record is clear that such necessarily implication is true; in fact, the record supports that it is false.

### ii. ChromaDex's Funding and Scientific Research

Elysium's Counterclaim also alleges that ChromaDex "proudly advertises that it 'pioneered NAD research by investing millions of dollars in safety and human clinical trials on its patent protected NR' and claims to have supplied NR to 'over 160 leading institutions for research." Counterclaim ¶ 149. It claims that the statements are false; they create "the misleading impression that ChromaDex has funded or is funding more than 160 studies relating to NR" when in fact it "admit[ed] on a November 10, 2016 earnings call that 'It's also important to note that ChromaDex is not paying for these studies . . . . " Id.

Elysium relies for its claim of falsity on a January 2017 slide deck and an accompanying email chain from Jaksch. It claims that the documents demonstrate, or at least create a genuine fact issue, that ChromaDex's claim to have invested millions of dollars in research is false. For its part, ChromaDex offers evidence of the truth of the statement regarding the investment of millions of dollars. It points to its 2018 10-K filing which states that "[r]esearch and development costs for the fiscal years ended [sic] December 31, 2018, and December 30, 2017, were approximately \$5.5 million and \$4.0 million, respectively." ChromaDex, Annual Report (Form 10-K) (March 7, 2019) at 13.<sup>21</sup>

<sup>21</sup> The filing is not in the su

<sup>&</sup>lt;sup>21</sup> The filing is not in the summary judgment record; ChromaDex references the publicly available document for the first time in its reply briefing. Dkt. No. 262 at 7. However, "[c]ourts resolving summary judgment motions regularly accept SEC filings for the truth of their contents." *Donoghue v. Astro Aerospace Ltd.*, 2021 WL 1964294, at \*1 (S.D.N.Y. May 17, 2021); *see also Desclafani v. Pave-Mark Corp.*, 2008 WL 3914881, at \*5 n.7 (S.D.N.Y. Aug. 22, 2008) ("Because courts may take judicial notice of the contents of filings with the [SEC], and 'any facts subject to judicial notice may properly be considered in a motion for summary judgment,' I take judicial notice of the contents of [a filed] Proxy Statement and consider it for the purposes of this motion." (internal citations omitted) (quoting *Fed. Election Comm'n v. Hall-Tyner Campaign Comm.*, 524 F. Supp. 955, 959 n.7 (S.D.N.Y. 1981))).

Because the burden at trial would be on Elysium at trial to demonstrate that the statements it challenges are literally true, once ChromaDex, as the moving party, has pointed to the absence of such evidence, Elysium must identify evidence to create a genuine issue of fact at the summary judgment stage. *Jaramillo*, 536 F.3d at 145; *Wright*, 554 F.3d at 266. It has failed to discharge that duty.

The statements to which Elysium points relate to specific projects and the investment ChromaDex made in those projects and not to ChromaDex's research investments as a whole. In a slide deck that Elysium points to entitled "Investor Presentation," ChromaDex states that it engaged in "[m]ore than 100 pre-clinical and clinical studies [that] represent over \$50 million of non-paid research for ChromaDex." Dkt. No. 251, Ex. NN at 21. Elysium also points to an email chain in which Jaksch sends "a current copy of our investor deck," along with accompanying text providing additional information about the slides. Dkt. No. 251, Ex. OO at 13. The deck includes a slide detailing ChromaDex's collaborative agreements on Niagen with universities and research institutions that "either currently or will soon be conducting studies surrounding various specific possible health benefits related to NR," and the accompanying text flags that "[i]t's also important to note that ChromaDex is not paying for any of this research."

Id. The antecedent for "this research" is the particular collaborative agreements. The comment states that ChromaDex is "not paying for any of this research," not that ChromaDex is not paying for any research at all.<sup>22</sup>

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<sup>&</sup>lt;sup>22</sup> Elysium also points to testimony of Dellinger that when he was employed by ChromaDex, he was told by Jaksch that "clinical research was not a company priority" and that "clinical studies don't mean anything," and that he was directed by Jaksch to "facilitate as many free pre-clinical and clinical studies with third-party researchers as possible," to which end Dellinger "facilitated a significant number of 'material transfer agreements' where ChromaDex would provide NR to third parties to use in their research." Dkt. No. 252 ¶¶ 4–5. Dellinger also testified that the value of the NR donated pursuant to these agreements was not "millions of dollars' worth," because "at

# b. Statements Regarding the Safety and Efficacy of ChromaDex's Products

Elysium's Counterclaim alleges that various statements made by ChromaDex about the safety and efficacy of Niagen and Tru Niagen are false.

# i. Tru Niagen Increases NAD+ Levels by 40–50%

First, Elysium's Counterclaim alleges that ChromaDex falsely advertises that Tru Niagen increases NAD by 40–50%. Counterclaim ¶¶ 10, 45–46. ChromaDex's website includes a graphic that states:

• "Tru Niagen increases NAD by 40–50%" along with the qualifier that this is "on average at 300 mg / day for 8 weeks," and a citation to the 2019 Conze Study. Dkt. No. 245, Ex. LLL.

ChromaDex asserts that this statement is true, because "the Conze Study did in fact show that NIAGEN increased NAD levels by 40-50% on average after eight weeks in study participants taking a 300 mg daily dose, the recommended daily dose of Tru Niagen." Dkt. No. 210 at 15. Elysium responds that the Conze Study is unreliable to establish this proposition. Dkt. No. 250 at 12–13.

A similar standard applies to Elysium's allegations regarding ChromaDex's statements that applied to ChromaDex's challenges to Elysium's statements regarding the outcome of the studies it cited. Because the challenged statement cites to the Conze Study, Elysium must demonstrate a genuine issue of fact whether the study "is not sufficiently reliable to permit one to conclude with reasonable certainty that [it] established the claim made." *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d at 1549; *McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F. Supp. 2d at

the time [h]e worked at ChromaDex, it could manufacture 1 kilogram of NR for approximately Id. ¶ 6. But that testimony, even construed favorably to Elysium as it must on this motion, does not establish that ChromaDex did not make millions of dollars out investments outside of the agreements.

248–49. Elysium does not dispute that the results of the Conze Study showed that Niagen increased NAD+ levels at a 300 mg dose; however, it argues that those results are unreliable because the Conze Study artificially depleted participants' NAD+ levels before the study began. Dkt. No. 250 at 13.

The Conze Study included a two-week run-in period and an eight-week supplementation period. Dkt. No. 230, Ex. 15 at 2. The study explains that "[t]o minimize the effect of dietary influences on NAD+ metabolite levels, subjects were instructed to avoid foods that contain high amounts of tryptophan and forms of vitamin B3 during the run-in and NR supplementation periods." *Id.* The study's clinical protocol, which lists Dellinger in his then-capacity as ChromaDex's Director of Scientific Affairs as the sponsor contact, *see* Dkt. No. 251, Ex. EEE at 1, included an extensive list of "foods to avoid/limit during the study," explaining that the "goal [was] to standardize the ingestion of niacin equivalents to approximately 20 mg/day throughout the study," and that "[s]ubjects will be instructed to ensure that they are consuming greater than 16 mg/day with the goal of approximately 20 mg/day," *id.* at 32. Foods to avoid included poultry, fortified breads and bread products, fortified ready-made cereals, energy drinks, soy products (excluding tofu), and other game; foods to limit included beef, pork, eggs, milk and dairy products, seeds and nuts, fish, lobster, and crab. *Id.* 

At deposition, Kruger—one of the study's authors and, at the time of the study, President of Spherix Consulting Inc., which provided scientific and regulatory consulting to ChromaDex—stated that the purpose of the run-in period was "to take out the variability in baseline levels amongst subjects." Dkt. No. 230, Ex. 20 at 186. She conceded, however, that the study did not account for potential effects of this diet protocol on NAD+ levels, testifying that "we cannot

draw a conclusion as to what a dietary control over two weeks would do to NAD levels." Dkt. No. 251, Ex. PP at 192.

Dellinger, who at the time and as noted above was employed at ChromaDex as its

Director of Scientific Affairs and was listed as the sponsor contact on the study protocols, but
who is now employed by Elysium as their Vice President of Scientific Affairs, submitted a
declaration in which he calls into question to the reliability of the Conze Study. Dkt. No. 252.

He states that:

In or around mid-2015, after ChromaDex received the initial test results from the Trammell Study showing that a 300 mg dose of NR did not significantly increase NAD+ levels, Dr. Kruger shared with me her hypothesis that NR supplementation cannot increase NAD+ levels unless such NAD+ levels are already depleted. Dr. Kruger advocated for ChromaDex to design a study in which participants' NAD+ levels were artificially depleted through dietary restrictions in order to show an increase when NR was administered.

Id. ¶ 10. In his account, the Conze Study was manipulated to reach a preordained result. He states that, when the study was being designed, Kruger sent him two studies from 1989 demonstrating that NAD+ levels can be depleted through a diet limiting niacin and tryptophan intake, and that "a single administration of nicotinamide could increase NAD-related metabolites at the end of each dietary-restrictive period." Id. ¶¶ 11–12. He further states that

Thus, Dr. Kruger advocated that ChromaDex design a study to restrict participants' niacin and tryptophan intake in advance of the administration of NR in order to deplete the participants' NAD+ levels, as shown in the 1989 Studies. Then, administration of NR would replenish those depleted NAD+ levels, also as shown in the 1989 Studies, which would create the impression of a significant increase in NAD+ levels rather than a return to normal levels. Dr. Kruger convinced ChromaDex to design such a study, which was ultimately published on July 5, 2019 as the "2019 Conze Study." Further confirmation that the 2019 Conze Study was modeled after the 1989 Studies, the 2019 Conze Study cites the Fu 1989 Study for its statistical power calculation. They could not use the data for the power calculation unless they were planning to lower NAD+ levels on purpose just like the 1989 Studies. Also Figure 3A in the 2019 Conze Study clearly shows that NAD+ levels of the placebo group decrease significantly during the study demonstrating a successful depletion of NE intake due to the dietary restrictions.

Id. ¶ 13. Finally, he states that he "opposed the design of the 2019 Conze Study because [he] thought it was unnecessary," because he "believed in the effectiveness of NR in a well-designed study," but he was overruled. Id. ¶ 14. He states that he nonetheless "refused to sign a clinical study protocol with a dietary restriction of 10.1 NE [niacin equivalents] per day (the 'low' group in the 1989 Studies) due to potential health risks to participants," and "insisted that participants receive[] at least 20 NE per day, the 'adequate' level of niacin intake, but still below normal dietary levels. Id.

ChromaDex's motion for summary judgment asserts that "there is no triable issue concerning the reliability of the Conze Study." Dkt. No. 262 at 8. It points out that Dellinger ultimately signed onto the study protocols as the study's sponsor contact and thus questions the credibility of Dellinger's later declaration, made after he switched to Elysium. It also points to evidence that the study was well-designed. <sup>23</sup> However, credibility is paradigmatically a jury question. *See, e.g., Altomare v. Wells Fargo Securities, LLC*, 2012 WL 489200, at \*9 (S.D.N.Y. Feb. 15, 2012) ("[I]t is not the role of the Court to make these credibility determinations on summary judgment; rather, it must assume that [the nonmoving party's] testimony will be credited and draw all reasonable inferences in [the nonmoving party's] favor." (internal quotation marks omitted) (quoting *Catalano v. Lynbrook Glass & Architectural Metals Corp.*, 2008 WL 64693, at \*9 n.5 (E.D.N.Y. Jan 4., 2008) (quoting *Shager v. Upjohn Co.*, 913 F.2d 398, 402 (7th Cir. 1990)))). And Elysium need only raise more than a "metaphysical doubt," *see* 

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<sup>&</sup>lt;sup>23</sup> Guarente testified that he reviewed the study and did not "have anything that would have caused [him] to question any portion of it." Dkt. No. 230, Ex. 21 at 19. Kruger testified that the protocol was designed only to reduce baseline variability, and that the protocol amount of niacin equivalent to consume was "well within the normal range." Dkt. No. 251, Ex. PP at 194. The Conze Study also was published and peer-reviewed. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593 (1993) (discussing peer review as one indicium of reliability).

Matsushita Elec. Indus., 475 U.S. at 586, to defeat summary judgment. If Dellinger's declaration is to be believed, then the study design was manipulated and biased, and there is reason to question "the objectivity . . . of the persons conducting the tests." Proctor & Gamble Co., 747 F.2d at 119. A jury, if it credited Dellinger's testimony, could find that the Conze Study was not designed objectively, and thus was not reliable to substantiate the proposition for which ChromaDex in its advertisement cites it—that Tru Niagen raises NAD+ levels by 40–50%. It follows that ChromaDex is not entitled to summary judgment on this point.

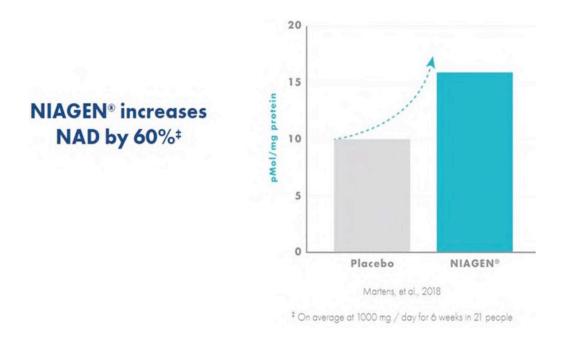
#### ii. Niagen increases NAD+ levels by 60%

Second, Elysium's Counterclaim asserts that before ChromaDex advertised that Tru Niagen raised NAD+ levels by 40–50%, it advertised on its website that the Martens Study showed that Niagen increased NAD+ by 60%. *See* Dkt. No. 210 at 17 (citing Counterclaim ¶¶ 11–12, 47). The Counterclaim includes a graphic stating that "NIAGEN® increases NAD by 60%," with a citation to the 2018 Martens Study and the qualifier that this is "[o]n average of 1000 mg / day for 6 weeks in 21 people." Counterclaim ¶ 47; *see also* Dkt. No. 210 at 17.

The Martens Study was a 2 x 6 week randomized, double-blind, placebo-controlled, crossover clinical trial of Niagen. Dkt. No. 230-14 at 1. In the study, participants were randomized into one of two groups: Group A received placebo capsules during the first six weeks of the study and then crossed over to receive NR capsules at a dosage of 500 mg twice a day, i.e., 1000 mg per day, for the remaining six weeks. Group B did the opposite, receiving NR capsules first and then placebo capsules for the last six weeks. *Id.* at 3–4. The study found that "NR was well tolerated at the dose tested, and no serious adverse effects occurred." *Id.* at 4. It concluded that "[o]ral NR supplementation effectively elevated levels of NAD+ in [peripheral blood mononuclear cells] by ~60% compared with placebo." *Id.* at 3.

ChromaDex argues that the Martens Study substantiates the claim made and thus that it is entitled to summary judgment. Elysium does not dispute that the Martens Study itself showed that Niagen, at a 1000 mg per day dose, increased NAD+ levels by 60%. In its Counterclaim, Elysium alleged that the Trammell Study, which preceded the Martens Study, "debunked this claim," because it showed "no statistically significant increase in NAD levels even at an intake of 1,000 mg per day." Counterclaim ¶ 48. In its opposition to ChromaDex's summary judgment motion, however, Elysium no longer repeats this specific claim, and the Court therefore deems it abandoned. It contests ChromaDex's motion for summary judgment as to this statement only on the basis that ChromaDex's "argument that the falsity is clarified by a small notation on the graphic is misplaced." Dkt. No. 250 at 17 n.4. Elysium relies on Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH, 2015 WL 4002468, at \*19 (S.D.N.Y. July 1, 2015), for the proposition that "as many courts have found, a footnote or disclaimer that purports to change the apparent meaning of the claims and render them literally truthful, but which is so inconspicuously located or in such fine print that readers tend to overlook it, will not remedy the misleading nature of the claims." *Id.* 

Elysium's argument is not well-founded for two independent reasons, and ChromaDex is entitled to summary judgment. First, the notation that the results are "[o]n average of 1000 mg/day for 6 weeks in 21 people" does not "purport to change the apparent meaning of the claims and render them literally truthful"; the claim at issue here is literally true, and the notation merely explains the parameters in which it is true. Second, the notation is not "a footnote or disclaimer" that is "inconspicuously located or in such fine print that readers tend to overlook it." It is the only other text on the graphic, displayed immediately below the graphic itself.



ChromaDex is thus entitled to summary judgment on this claim—there is no evidence that the challenged statement is anything other than literally true.

#### iii. October 2014 Press Release

Next, Elysium's Counterclaim asserts that in an October 25, 2018 press release,

ChromaDex stated that "Niagen was clinically-studied at 300 mg to increase NAD in 2016,

published in the journal *Nature Communications*." Dkt. No. 210 at 19 (citing Counterclaim ¶¶ 9,

14). Elysium's Counterclaim alleges that "[t]he Trammel Study demonstrated that Tru Niagen

does *not* work to raise NAD levels." Counterclaim ¶ 46. The parties' Joint 56.1 Statement of

Undisputed Facts states that "[t]he Trammell Study reported that a single dose of NR increased

NAD+ levels in blood over a 24-hour period," and that "[t]he Trammell Study reported

dose-dependent increases in NAD+ levels following administration of 100, 300, and 1000 mg

single doses of NR in adults." Joint 56.1 ¶¶ 10–11. ChromaDex reasons based on this that

"Elysium appears to have withdrawn this claim." Dkt. No. 210 at 19. Indeed, in its opposition

papers, Elysium does not reference its allegations regarding this press release directly. With

regard to the Trammell Study, it no longer puts forward the blanket assertion that the Trammell

Study did not show that Tru Niagen (or, Niagen at a 300 mg dose) raises NAD+ levels at all, but rather repeatedly emphasizes—in other contexts—that "[t]he Trammell Study did not show a *statistically significant increase* in NAD+ levels in participants taking 300 mg/day of NR." Dkt. No. 250 at 3; *see also id.* at 13. To the extent that Elysium has not withdrawn its claim as to the falsity of the statement that "Niagen was clinically-studied at 300 mg to increase NAD in 2016," by virtue of its concession in the Joint 56.1 Statement that the Trammell Study did report that NR dose-dependently raised NAD+ levels in 100 mg, 300 mg, and 1000 mg doses, ChromaDex is entitled to summary judgment on this claim. It is literally true that "Niagen was clinically-studied at 300 mg to increase NAD in 2016." Elysium cannot argue that it is simultaneously true, as the Joint 56.1 states, that the Trammell Study showed a dose-dependent increase in NAD levels at 300 mg but that the study is also not sufficiently reliable to establish that exact proposition with reasonable certainty.

Elysium does not argue that the statement either expressly or necessarily and unambiguously conveyed that the increase was statistically significant. Nor does it identify any extrinsic evidence to demonstrate implied falsity. Had the press release asserted that Niagen was therefore *effective*, or something else along those lines, it might be relevant that the results of the Trammell Study did not show a statistically significant increase, but the press release makes no such statement. Accordingly, ChromaDex is entitled to summary judgment.

## iv. Other NAD-Dependent Clinical Study Results

ChromaDex further asserts that it is entitled to summary judgment as to Elysium's allegation that "ChromaDex makes other statements that 'depend on the false premise that Tru Niagen increases NAD,' and are thus 'rendered false by the falsity of the fundamental proposition on which they rest, that Tru Niagen increases NAD." Dkt. No. 210 at 19 (quoting Counterclaim ¶ 54). Neither party makes clear exactly what statements fall into this category.

However, ChromaDex's sole argument is that "Elysium's claim fails for the same reasons the claims addressed above fail—namely, that abundance of clinical studies demonstrating that NIAGEN and TRU NIAGEN do raise NAD levels." *Id.* The Court has denied summary judgment as to the reliability of the Conze Study. The Court has also rejected ChromaDex's arguments about the Dollerup Study and the Martens Study, because they tested a 1000 mg dose and 2000 mg dose of Niagen, respectively. The Court further noted that while the Trammell Study undisputedly demonstrated that Niagen raises NAD+ levels, the evidence is similarly undisputed that it did not do so at a statistically significant level. Because ChromaDex's motion for summary judgment as to this point relies solely on its previous arguments about its various clinical studies which the Court has rejected, summary judgment is not warranted.

### v. Safety and Trustworthiness of Tru Niagen

Elysium's Counterclaim also alleges that "ChromaDex falsely touts Tru Niagen as 'safe' and 'trusted," Counterclaim ¶¶ 62–83, in the following statements:

- Advertising that Tru Niagen is "the Trusted NAD Supplement." *Id.* ¶ 64.
- A statement made "[s]hortly before publication of the trial" in ChromaDex's updated Tru Niagen Amazon.com advertising, which claims that "more than 4 published trials have confirmed Tru Niagen is safe and effective," and "currently advertises its product as 'SAFE TO USE' with 'NO known negative side effects.'" *Id.* ¶ 65.
- A press release announcing the clinical trial results and containing the following statements:
  - a. "The results of this large human trial directly support the efficacy and safety of our NAD-boosting consumer product Tru Niagen,' says ChromaDex CEO Rob Fried.
  - b. 'The study also joints previous chronic supplementation studies to support the safety of chronic Niagen supplementation.'" Id. ¶ 66 (citing Ex. 1).

- A statement by Charles Brenner in an article on the "Investor Relations" page of the ChromaDex website about the Conze Study that: "This is a timely publication in the history of Niagen as it clearly shows safe, dose-dependent and time-dependent increases in blood NAD in human populations," and "[w]ith so much global interest in NAD-boosting supplementation strategies, our approach to human translation has been to put safety first." *Id.* ¶ 67 (citing Ex. 1).
- A statement in a blog post on blog.truniagen.com that "Tru Niagen is a safe, effective supplement" and that the Conze Study "further validates the safety and efficacy of Tru Niagen." *Id.* ¶ 68 (citing Ex. 2).

The Counterclaim also alleges that these "false claims of its product's safety" are "paired with affirmative attacks on Elysium and Basis," which juxtaposition "seeks to convince consumers that no harm will come to them as a result of their ingestion of ChromaDex's product and that Tru Niagen is in fact 'the Trusted NAD Supplement' and more trustworthy than Elysium's basis," which they allege is "false and misleading." *Id.* ¶ 70–72.

Elysium alleges that the statements are false: "the July 2019 Conze Study shows that Tru Niagen is clinically proven to injure consumers by dramatically decreasing their white blood cell count (WBC), posing serious risk to consumers, particularly the elderly customers who might be most attracted to ChromaDex's supposed 'anti-aging' product." *Id.* ¶ 62. Elysium contends: "[i]n reality, Tru Niagen is far from safe and trustworthy, as established by ChromaDex's own clinical trial, which showed that Tru Niagen is unsafe and dangerous to consumers," because of the alleged white blood cell count decrease shown in the study. *Id.* ¶ 73.

The Conze Study reports a statistically significant decrease in the white blood cell count of patients taking 300mg of NR (the dosage of Tru Niagen) compared to placebo:

Hematology and clinical chemistry. Some differences were observed in the hematology parameters at day 56 (Table 3, Supplemental Figure). Specifically, decreases occurred in the white blood cell count and the monocyte count in the placebo-treated group, white blood cell, neutrophil, and lymphocyte counts in the 100 mg-treated group, white blood cell, neutrophil, lymphocyte, monocyte, and basophil counts in the 300 mg-treated group, and the white blood cell, neutrophil, and lymphocyte counts in the 1000 mg-treated group. . . . Statistically significant

differences also occurred in the white blood cell count in the 300 mg group compared to the placebo-, 100 mg-, and 1000 mg-treated groups . . . .

Dkt. No. 230, Ex. 15 at 8. The study reported its findings in each group in a table that presented mean levels (x 10<sup>9</sup>/L) at screening and at day 56, as well as the change from screening, plus/minus the standard deviation. Id. at 9. With regard to white blood cell count, the study's specific findings were that in the placebo group, white blood cell counts went from  $6.31 \pm 1.21$ to  $5.83 \pm 1.25$ , representing a change of  $-0.49 \pm 1.13$ ; in the 100 mg of Niagen group, white blood cell counts went from  $6.29 \pm 1.63$  to  $5.65 \pm 1.68$ , representing a change of  $-0.59 \pm 0.84$ ; in the 300 mg of Niagen group, white blood cell counts went from  $6.17 \pm 1.45$  to  $4.96 \pm 1.01$ , representing a change of  $-1.10 \pm 1.29$ ; and finally, in the 1000 mg Niagen group, white blood cell counts went to  $6.54 \pm 1.90$  to  $5.69 \pm 1.41$ , representing a change of  $-0.99 \pm 1.23$ . *Id.* With regard to the neutrophil<sup>24</sup> count, in the placebo group, neutrophil counts went from  $3.63 \pm 0.96$  to  $3.34 \pm$ 1.00, representing a change of  $-0.31 \pm 0.96$ ; in the 100 mg of Niagen group, neutrophil counts went from  $3.52 \pm 1.12$  to  $3.11 \pm 1.12$ , representing a change of  $-0.41 \pm 74$ ; in the 300 mg of Niagen group, neutrophil counts went from  $3.68 \pm 1.23$  to  $2.78 \pm 0.96$ , representing a change of - $0.82 \pm 1.22$ ; and finally, in the 1000 mg Niagen group, neutrophil counts went from  $3.83 \pm 1.26$ to  $3.17 \pm 0.93$ , representing a change of  $-0.76 \pm 0.96$ . *Id*.

The Study concluded that "[i]mportantly, the differences were not dose-dependent, within the healthy clinical reference ranges for the laboratory and clinic location, and deemed to be not clinically meaningful or an AE [adverse effect]." *Id.* Its bottom-line conclusion was that "[o]ral NIAGEN is safe and well-tolerated up to 1000mg/day for 8 weeks." *Id.* 

<sup>&</sup>lt;sup>24</sup> Neutrophils are a type of white blood cell; Merriam-Webster defines neutrophil as "a granulocyte that is the chief phagocytic white blood cell of the blood." Merriam-Webster Online Dictionary, accessible at https://www.merriam-webster.com/dictionary/neutrophil (last accessed February 3, 2022).

The 2020 Marinescu Study, a toxicity study of Elysium's NR conducted by, among others, Guarente, Morris, and Dellinger of Elysium, cites the Conze Study along with various other studies for the proposition that "[s]ubsequent human clinical studies have demonstrated the safety and tolerability of NR at doses up to 2,000 mg/d for 12 weeks and confirmed the efficacy of NR for inducing NAD+ biosynthesis." Dkt. No. 230, Ex. 18 at 308.

At deposition, however, Guarente expressed some hesitation about the decrease in neutrophil levels that the study revealed:

- Q. Did you have anything that would have caused you to question any portion of [the Conze Study]?
- A. There's a lot of data here.

(Witness reviews document.)

No. The one thing I remember noticing in this study is the effect on neutrophils.

- Q. And what did you notice about the effect on neutrophils?
- A. It looked like there was a dose-dependent decline in neutrophils.
- Q. What's a neutrophil?
- A. It's a white blood cell.

Dkt. No. 230, Ex. 21 at 209.

Elysium argues that the decreases in white blood cell count in the Conze Study show that Tru Niagen is unsafe. It offers an unauthenticated copy of what purports to be a page from the Leukemia & Lymphoma Society website that includes a table of "normal ranges of blood cell counts for healthy adults and children." Dkt. No. 245, Ex. RR. According to the table, the normal range of white blood cells per microliter of blood in men is 5,000 to 10,000 (which is, in the metric used by the Conze Study, 5.0 to 10.0 x 10<sup>9</sup>/L) and the normal range of white blood cells per microliter of blood in women is 4,500 to 11,000 (4.5 to 11.0 x 10<sup>9</sup>/L). *Id.* It also states

that neutrophils should typically make up 55% to 70% of white blood cells. *Id.* Elysium argues, based on this, that for participants taking 300 mg per day of Niagen—i.e., Tru Niagen—"the *average* WBC count dropped to  $4.96 \pm 1.01$ , meaning the average WBC count could be as low as 3.95—below the normal healthy range for men [5.0 to 10.0]." Dkt. No. 250 at 15. It adds that "the results were also at the lower bound of the normal healthy range for women, which suggests that many participants' [sic] showed abnormally low WBC counts, but such data was concealed through averaging." *Id.* at 15–16.

ChromaDex responds that the cited webpage does not suggest that any deviation from the normal range is "unsafe," and reiterates that the Conze Study itself found that deviations in white blood cell counts were "within the healthy clinical reference ranges for the laboratory and clinic location, and deemed not to be clinically meaningful or an [adverse event]." Dkt. No. 262 at 10–11.

ChromaDex's argument is well-taken. A jury could find, relying on the fact that the study showed declines in white blood cell counts and Guarente's testimony about the potential dose-dependency of the neutrophil decline, that the study did raise a concern that there was a relationship between Niagen and white blood cell counts. A jury could not find, however, based only on a web page purporting to show "normal" white blood cell count ranges along with speculation that "the average WBC count *could* be as low as 3.95," that the study demonstrated that white blood cell counts in people taking Tru Niagen dropped below the "normal" range. Nor could the jury find, based on the evidence in the summary judgment record—or rather, the lack thereof—that white blood cell counts that are at the low end of normal or slightly below normal are *unsafe*. Such a conclusion requires a leap that is unsupported by the evidence. The jury would have to speculate. A plaintiff prosecuting a Lanham Act claim "must show falsity,

not merely uncertainty." *Apotex*, 823 F.3d at 66. As such, ChromaDex is entitled to summary judgment on this claim.

# c. Statements Regarding FDA Regulation of ChromaDex's Products

Elysium's Counterclaim further alleges that "ChromaDex falsely advertised that Tru Niagen had been rigorously reviewed for safety and efficacy by the FDA, when in fact, FDA did neither." Counterclaim ¶ 105–135. Broadly, its claims fit into three categories: (1) that ChromaDex's advertisements represent that the FDA reviewed Niagen for efficacy in connection with ChromaDex's GRAS and NDI submissions, when in fact both of those submissions relate only to safety and not to efficacy, *see id.* ¶ 131–135; (2) that ChromaDex's GRAS and NDI submissions related only to Niagen, not Tru Niagen, *see id.* ¶ 130; and (3) that the FDA does not conduct an independent safety review of GRAS and NDI submissions for safety, *see id.* ¶ 106–113. ChromaDex moves for summary judgment on all three of these categories; in its opposition, Elysium defends only the first two. As such, the Court deems Elysium to have abandoned its argument that the FDA conducted no safety review of Niagen in connection with ChromaDex's GRAS and NDI submissions.<sup>25</sup>

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<sup>&</sup>lt;sup>25</sup> Even if Elysium had not abandoned this argument, it would not be successful. The record is undisputed that the FDA does conduct an independent review in connection with such submissions and does not merely "accept those submissions," as Elysium initially alleged, *see* Counterclaim ¶ 108. Both parties' experts—Martin for Elysium and Weisman for ChromaDex—testify extensively about the FDA's review process in connection with GRAS submissions. *See* Dkt. No. 230, Ex. 12 ("Martin Dep.") at 64–70 (explaining that under the current FDA GRAS notification system, the "FDA would review that document, review the safety of it and so forth," and that "[t]he people involved in that would be a consumer safety officer, a chemist, toxicologist, sometimes a microbiologist, sometimes a food scientist, sometimes a nutritionist," and calling the FDA's review "thorough"); Dkt. No. 230, Ex. 11 ("Weisman Report") (explaining that "[w]hen the FDA receives a notice, it evaluates whether the submitted notice is sufficient for a GRAS determination or whether the information in the notice (or otherwise available) raises potential questions on whether the substance is indeed GRAS," and then either "respond[s] without question to the GRAS conclusion (by issuing a 'no objection' letter) or . . . conclude[s] the notice does not provide sufficient evidence of a GRAS conclusion"). Weisman

The motion for summary judgment with respect to statements in the first category is granted in part and denied in part. Elysium's claim has two components: It challenges ChromaDex's historical advertising that the GRAS and NDI submissions that the submissions included testing for efficacy and it challenges ChromaDex's current advertising which does not explicitly reference efficacy but that, according to Elysium, "gives consumers the false impression that Tru Niagen has been reviewed for effectiveness by the FDA." Dkt. No. 250 at 16.

As to the first of these, ChromaDex's website historically stated:

• "NIAGEN® is the only nicotinamide riboside that has been rigorously tested for safety and efficacy with the US FDA GRAS (Generally Recognized As Safe) and two 'New Dietary Ingredient' (NDI) Notifications." Counterclaim, Ex. 6.

ChromaDex does not dispute that GRAS and NDI submissions relate only to safety and not to efficacy. ChromaDex's submissions related to Niagen's use as a food ingredient and not as a drug. ChromaDex also does not dispute that it published and used the statement that appears in Exhibit 6. Accordingly, summary judgment with respect to this statement is denied.

The second set of challenged statements present a closer question. ChromaDex's current advertising includes the following statements:

- "Why NIAGEN®" followed by bulleted list that includes "3 FDA Safety Reviews." Counterclaim, Ex. 5.
- "Niagen is the world's first and only known FDA-safety reviewed form of NR." Counterclaim, Ex. 8.
- "Niagen®, the sole active ingredient in Tru Niagen® from ChromaDex, was successfully notified to the U.S. FDA as Generally Recognized as Safe (GRAS) and as a New Dietary Ingredient (NDI)."

also describes the FDA's NDI notification review process, Weisman Report at 10, and both experts testified that NDI notifications have a high failure rate, *id*.; Martin Dep. at 54.

The statements refer exclusively to safety. They do not mention efficacy. Elysium argues that the statements nonetheless "giv[e] consumers the false impression that Tru Niagen has been reviewed for effectiveness by the FDA." Dkt. No. 250 at 16. It supports the argument by the testimony of its survey expert, Brian Sowers, who conducted a survey which found that there are "a net 23.3% of respondents who take away the mistaken belief that the FDA has reviewed Tru Niagen for effectiveness" from viewing the Tru Niagen homepage.<sup>26</sup>

The Second Circuit has held that representations in advertising that are "commensurate with information in an FDA label generally cannot form the basis for Lanham Act liability." *Apotex*, 823 F.3d at 64. The only caveat it has offered is that "Lanham Act liability might arise if an advertisement uses information contained in an FDA-approved label that does not correspond substantially to the label, or otherwise renders the advertisement literally or implicitly false." *Id.* at 64 n.10. The Circuit has explained that the "principle rightfully insulates pharmaceutical companies from liability when they engage in First Amendment speech that is consistent with the

<sup>&</sup>lt;sup>26</sup> ChromaDex's argument that the Sowers survey is not relevant because the Counterclaims refer to "a previous version of the 'Unauthorized NR' page on ChromaDex's Tru Niagen website [which] included a statement that 'NIAGEN® is the only nicotinamide riboside that has been rigorously tested for safety . . . with the US FDA GRAS (Generally Recognized as Safe) and two "New Dietary Ingredient" (NDI) notifications," which is Exhibit 6 to the Counterclaim, whereas "the Sowers report tests a completely different page—the Tru Niagen website's homepage as it appeared when the Sowers Survey was conducted—which makes no reference to efficacy," Dkt. No. 210 at 27 (omission in original), is unavailing. The omitted phrase, as quoted in full in Elysium's Counterclaim and as seen in Exhibit 6, is "has been rigorously tested for safety and efficacy with the US FDA [GRAS] and two [NDI] notifications." Counterclaim ¶ 111, Ex. 6. The Sowers survey did not test whether this statement *implied* to consumers that the FDA reviewed Niagen for efficacy; the statement explicitly states this and is thus subject to a challenge of literal falsity, not implied falsity. Rather, the Sowers survey seeks to demonstrate that statements about FDA review of Niagen that do not explicitly reference efficacy nonetheless convey to consumers that the FDA has reviewed Niagen for efficacy, and thus are impliedly false; thus, it is proper that that the Sowers survey tested statements "which make[] no reference to efficacy," see Dkt. No. 210 at 27.

directive of the regulatory body having oversight of product labels" and is necessary "to avoid chilling speech that ought to be protected." *Id.* at 64.

The same principles apply to and foreclose Elysium's claim based on ChromaDex's communication that it was "safety-reviewed" by the FDA or successfully notified as GRAS. The Congress (and the FDA) have determined that nutritional ingredients—unlike drugs—are only to be reviewed for safety and not for effectiveness. If the challenged statements regarding GRAS and FDA review for safety could have led consumers to any confusion that the FDA also reviewed the product for efficacy, such confusion could have been based only in confusion about the FDA and what it means for the FDA to review a nutritional product. It could not have resided in anything that ChromaDex said about the FDA review of its product. It did not say anything other than that FDA reviewed its product for safety and that Tru Niagen was notified as GRAS and as an NDI, not anything about efficacy. In these circumstances, to hold that ChromaDex or any other company could be held liable for statements such as these based on the notion that while they refer only to safety they could be understood to mean efficacy would "chill" all companies from informing the public that their nutritional products have been reviewed by or notified to the FDA and would run counter both to the FDCA and to First Amendment principles.

# d. Statement that ChromaDex is the Only Seller of NR

Elysium alleges that ChromaDex "falsely represents to consumers . . . that ChromaDex is the only seller of NR, which according to the website, can only be found under ChromaDex's trade name, 'Niagen.'" Counterclaim ¶ 94. The website states, under the heading "Look For NIAGEN® on the Label":

• "NR is a patented ingredient, only sold as NIAGEN®. ChromaDex holds the patent rights to NR, and sells the ingredient to consumers as TRU NIAGEN®." Dkt. No. 201 at 25 (citing Dkt. No. 192, Ex. 7).

• "If you are taking or plan to purchase an NR supplement, look at your label to ensure 'NIAGEN®' appears under the 'Supplement Facts.' Any nicotinamide riboside product that does not say 'NIAGEN®' on its label does not contain nicotinamide riboside that has been successfully notified to the FDA." *Id.* (citing Dkt. No. 192, Ex. 7).

Both parties move for summary judgment. Elysium argues that the statement that NR is a patented ingredient only sold as Niagen and that ChromaDex holds the patent rights to NR is false because "[t]he NR in Basis is not 'counterfeit' or 'inauthentic.' NR exists in nature. ChromaDex does not own a patent on NR. It licenses a patent for one method of manufacturing NR. While methods of manufacturing NR may vary, NR is NR." Dkt. No. 222 at 24. ChromaDex responds by arguing that it "does not state anywhere on the page that it is 'the only seller of NR." Dkt. No. 210 at 25. It claims that the advertisement should be read to state "that ChromaDex's NR is only sold as NIAGEN and that NIAGEN is the only nicotinamide riboside that has been successfully notified to the FDA as GRAS and successfully reviewed twice under the FDA's NDI notification program." *Id*.

The advertisement is not capable of being read as ChromaDex now would read it. It does not state, as ChromaDex suggests, that "*ChromaDex's NR* is only sold as NIAGEN," Dkt. No. 210 at 25 (emphasis added). As Elysium points out, it states "*NR* is a patented ingredient, only sold as NIAGEN®," Dkt. No. 192, Ex. 7 (emphasis added), without any qualifier that this statement refers only to ChromaDex's NR and not NR in general. *See* Dkt. No. 250 at 9. Moreover, the website uses "NR" as shorthand for nicotinamide riboside, not ChromaDex's NR. *See* Dkt. No. 192, Ex. 7 at 1 ("How to tell if your nicotinamide riboside (NR) supplement is authentic, and why you should know whether your product is counterfeit."). The advertisement unambiguously conveys that ChromaDex is the only seller of NR and that NR is only sold as Niagen.

ChromaDex does—and cannot—not claim that it held a patent to all NR or that NR was only sold as Niagen. The evidence demonstrates that NR exists naturally and that it is also sold in dietary supplements that do not contain Niagen. The record is devoid of evidence to the contrary. Elysium has established that there is no genuine dispute that the statement is literally false. ChromaDex's motion for summary judgment as to this claim is denied, and Elysium is entitled to summary judgment on this claim.

#### e. Statements that Basis is Inauthentic, Unsafe, and Ineffective

Elysium moves for partial summary judgment on liability on its affirmative false advertising claims related to what it calls the "Counterfeit Page," a page on ChromaDex's website. Elysium characterizes the page as "dedicate[d] . . . to attacking Elysium" and asserts that it "states that any NR product that is not sold by ChromaDex is 'counterfeit' and that NR is only sold as Niagen"; "directs customers to question any other NR product's authenticity, safety, and effectiveness"; "targets . . . directly at Basis by intentionally using an image similar to Basis's bottle on the website"; and was "updated . . . to expressly refer to Basis in its false comparison," to convey that "TruNiagen is authentic, safe, and effective, Basis is not." Dkt. No. 222 at 24. Elysium argues that it is entitled to summary judgment on liability on these claims because Basis is not counterfeit and is safe and effective.

The Counterfeit Page includes a large photo of a Tru Niagen bottle and pills, and an unlabeled white container and pills, with the captions "IS YOUR NICOTINAMIDE RIBOSIDE AUTHENTIC, SAFE, & EFFECTIVE?" and "How to tell if your nicotinamide riboside (NR) supplement is authentic, and why you should know whether your product is counterfeit."



Dkt. No. 213, Exs. S, T.

Underneath this graphic, the Counterfeit Page—as updated with references to Basis specifically—states:

As a science-based company for over 20 years, we value safety, accuracy and transparency, and that ingredients matter – especially when it comes to ingredients you put into your body. That is why it's important to clarify misleading marketing materials from Elysium Health's so-called "NR-E" ingredient. While the marketing language references "NR-E," that is not what was used in the 2017 study cited by Elysium. In fact, the study actually used Niagen® which was in Basis<sup>TM</sup> at the time (but is no longer). "NR-E" is a newly listed ingredient on the Basis<sup>TM</sup> label as of 2020, and there is no published, peer-reviewed human data on "NR-E" nor has it been reviewed by any regulatory bodies.

In contrast, Niagen®, the sole active ingredient in Tru Niagen® from ChromaDex, was successfully notified to the U.S. FDA as Generally Recognized as Safe (GRAS) and as a New Dietary Ingredient (NDI). In addition, Tru Niagen® has been approved for sale by Health Canada, the European Commission and Therapeutic Goods Administration (TGA) of Australia—four of the most stringent regulatory bodies in the world. Lastly, Niagen® is shown to safely and effectively increase NAD+ levels in 9 published human studies, which you can find listed on ClinicalTrials.gov.

Dkt. No. 213, Ex. T.

Elysium's motion for summary judgment does not focus on individual statements within these paragraphs, such as the statements pertaining to ChromaDex's FDA regulation or ChromaDex's clinical studies, but rather on its assertion that the Counterfeit Page represents that Basis is inauthentic, unsafe, and ineffective.

The record is undisputed that ChromaDex intended to communicate the message that Basis was inauthentic, unsafe, and ineffective. At deposition, then—ChromaDex CEO Jaksch testified at length about the Counterfeit Page:

- Q. Why is this page included on your website?
- A. To inform people that not all nicotinamide riboside is the same.
- Q. And you're saying that not all nicotinamide riboside is authentic, safe and effective; is that true?
- A. That's what it says.
- Q. And what products are you claiming are not authentic, safe and effective?
- A. Well, anybody that doesn't have nicotinamide riboside from ChromaDex.
- O. But do you identify any product specifically on this web page?
- A. Well in the paragraphs on the page that you said, it does, yeah.
- Q. What product does it identify?
- A. Well, it says Elysium Health so-called NRE.
- Q. And it talks about it being in Basis, right?
- A. Yeah, it says that.
- Q. So your claim is that Basis is not authentic, safe and effective, right?
- A. Yes.
- Q. And the picture on the cover image here, one is a bottle of Tru Niagen, the other is an unlabeled bottle. Is that supposed to be a bottle of Basis?
- A. Well, I don't know if Basis owns that bottle design or if Elysium owns that bottle design, but it's similar to Elysium's bottle design.

- Q. It was intended to appear like Basis, right? It looks like Basis, correct?
- A. Yes, it looks like it.

Dkt. No. 223, Ex. J at 88-90.

In the absence of extrinsic evidence, a Lanham Act plaintiff may establish the falsity of a communication only by demonstrating either that it is literally false, meaning the false message is explicitly stated, or that the false message is "conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated." *Time Warner Cable*, 497 F.3d at 158 (internal quotation marks omitted) (quoting Novartis Consumer Health, Inc. v. Johnson & Johnson–Merck Pharm. Co., 290 F.3d 578, 586–87 (3d Cir. 2002)); see also Church & Dwight, 843 F.3d at 66 (same). Elysium cannot establish that the Counterfeit Page explicitly conveys the message it contends is false. The page does not explicitly state that Basis—or even that all NR products not containing ChromaDex's NR—is inauthentic and counterfeit, unsafe, or ineffective. See Dkt. No. 213, Exs. S, T. It simply asks the question "IS YOUR NICOTINAMIDE RIBOSIDE AUTHENTIC, SAFE, & EFFECTIVE?" and conveys that ChromaDex's NR is authentic, safe and effective. Nor does the Counterfeit Page convey the proscribed message by necessary implication such that the audience would recognize the claim as it had been explicitly stated. On its face, the page simply flags potential concerns to look out for regarding the authenticity, safety, and effectiveness of NR-containing supplements other than Tru Niagen. It leaves open the possibility that other such supplements—including the supplement that is packaged in the unlabeled container on the page—may also be authentic, safe, and effective.

The Counterfeit Page conveys the message that Basis is inauthentic, unsafe, and ineffective by "clever innuendo." It suggests that while Tru Niagen and Niagen, which are named, are authentic, safe, and effective, the products of other companies (including that of

Elysium) are not. However, under Second Circuit law, a statement that may be false by innuendo but is susceptible to more than one reasonable interpretation must be supported by evidence that the intended message was the one that was actually received by the audience. *See American Home Products Corp. v. Johnson & Johnson*, 577 F.2d 160, 165 (2d Cir. 1978) (holding that representations that are not literally false, such as "clever use of innuendo, indirect intimations, and ambiguous suggestions . . . should usually be tested by the reactions of the public"). Elysium has not done so. Its motion thus must be denied.

#### C. Materiality

Both parties move for summary judgment on the other's claims, arguing that the other party has failed to adduce extrinsic evidence of materiality, and that such evidentiary deficiency is fatal to the claims. For the reasons that follow, the motions are both denied.

The motions squarely raise the question whether to establish what the courts have called materiality in a Lanham Act case, a plaintiff must produce extrinsic evidence that a challenged statement is likely to influence purchasing decisions or may rely on the nature and content of the statement alone to satisfy its burden. The two most recent Second Circuit cases that address materiality are *Apotex* and *Church & Dwight*.

In *Apotex*, the defendant had used a brochure in connection with its marketing of a pharmaceutical product that conflated two measures of concentration of the central ingredient of a drug in the blood of patients taking it in tablet form leading to an overstatement of the mean concentration of the product's central ingredient. The district court had concluded that the defendant "at most, . . . 'overstated the increase in mean tinzanidine plasma concentration' but that this evidence ultimately does not 'reveal anything about the impact on consumers' purchasing decisions." *Apotex*, 823 F.3d at 68 (quoting *Apotex Inc. v. Acorda Therapeutics*, *Inc.*, 2014 WL 5462547, at \*9 (S.D.N.Y. Oct. 23, 2014)). On appeal, the plaintiff argued that it

was not required to show that the relevant misrepresentation would have had an effect on consumers' purchasing decisions and that when a statement is literally false, consumer deception was presumed. The Second Circuit rejected those arguments. It concluded that the first argument ignored precedent from the Circuit that had endorsed a definition of materiality that the misstatement was likely to influence purchasing decisions and that the second argument conflated falsity with materiality. When a statement is literally false, a plaintiff may be relieved from presenting "extrinsic evidence showing consumer deception," but the plaintiff "is not thereby relieved of showing materiality." *Id.* at 68. The latter element "require[d] that the allegedly 'false or misleading representation involved an inherent or material quality of the product,' – i.e., that the representation was 'likely to influence purchasing decisions.'" *Id.* (quoting *Nat'l Basketball Ass'n*, 105 F.3d at 855 (internal quotation marks omitted)). Applying that materiality standard, the Circuit concluded that the district court had not erred in granting summary judgment and determining that the misrepresentation was not material. The Second Circuit reasoned:

This conclusion was sound; the only plausible effect attributable to the misrepresentation in the graph was an exaggeration of the scale of the mean drug concentration curves, or an improper conflation of the mean Cmax with the highest mean drug concentration for a given treatment. However, there is no record evidence that this inaccuracy would dissuade consumers from purchasing [the product]. Certainly, Apotex has provided none. Apotex's showing on this point consists of generalized evidence that Acorda's increased sales of [the product] stemmed from its advertisement efforts. Apotex fails to make the necessary showing that the specific misrepresentation in the graphic—in any of Acorda's advertisements—was likely to influence consumers' purchasing decisions.

Apotex, 823 F.3d at 68.

In *Church & Dwight*, which was issued just months after *Apotex*, the Second Circuit reviewed the district court's findings after a bench trial that defendant's misstatement was false and material and had caused injury. The product at issue was a pregnancy test. The defendant's

packaging and advertising had misrepresented the product's ability to measure pregnancy duration. The measure it used was different from the measure of pregnancy duration used in the medical profession. The defendant argued on appeal that the district court had failed to make findings necessary to support the conclusion of materiality. The district court had made findings as to injury and that the misstatement had related to an "inherent quality or characteristic" of the product that was a key feature that differentiated it from others in the market, but it did not make an explicit finding that the misstatement was likely to affect purchasing decisions. The Second Circuit identified that "the essential elements of the materiality standard" and, in particular, whether that standard required a finding of likelihood of an effect on purchasing decisions, was "somewhat unsettled" and that it "need not resolve that issue now." Church & Dwight, 843 F.3d at 70. In a footnote, however, the court stated that the Circuit had decided the issue that in the text it indicated was unsettled: "Apotex . . . recently settled the materiality standard in this Circuit, explaining that the standard is whether the deception is 'likely to influence purchasing decisions." Id. at 70 n. 11 (quoting Apotex, 823 F.3d at 63). The court rejected the appeal, holding that "the district court's conclusion, although uttered in connection with the element of likely injury, also constituted a finding that Defendant's misrepresentations were likely to influence purchasing decisions and were therefore material to Plaintiff's claim." *Id.* at 71. It emphasized that "the materiality of the falsity and the likelihood of injury to the plaintiff resulting from the defendant's falsity are separate essential elements," but concluded that "in many cases the evidence and the findings by the court that a plaintiff has been injured or is likely to suffer injury will satisfy the materiality standard—especially where the defendant and plaintiff are competitors in the same market and the falsity of the defendant's advertising is likely to lead consumers to prefer the defendant's product over the plaintiff's." Id.; see also id. at 71 ("If

consumers, faced with the choice to purchase either the plaintiff's product or the defendant's, are likely to prefer the defendant's product by reason of the defendant's false advertising, the falsity of the defendant's advertising is material to the plaintiff's Lanham Act claim.").

The court reasoned: "It is entirely reasonable to expect that for a significant number of women interested in learning whether they are pregnant—especially those who have not previously been pregnant or are otherwise ignorant of the details of the reproductive cycle—the information that Defendant's Product will tell them something different from what a doctor would provide would make them less likely to trust Defendant's Product, and more likely to purchase from Plaintiff, Defendant's closest competitor." *Id.* at 71. It then concluded that the evidence and the district court's findings that the plaintiff likely suffered a loss of sales by reason of the defendant's false advertising "adequately supported both the materiality element and the likely injury element." *Id.* 

Neither case directly answers the question whether and when extrinsic evidence is necessary to support a finding of materiality. *Apotex* involved the question whether evidence of literal falsity would alone establish materiality. The court answered that question in the negative, adding that the plaintiff had to establish that the misrepresentation involved an inherent or materiality quality of the product—a standard that it treated as equivalent to a likelihood that the misrepresentation would affect consumers' purchasing decisions. In affirming the district court's conclusion that the nature of the misrepresentation did not "reveal anything" about whether it would affect consumers' decisions, it noted the absence of "record evidence" that the misrepresentation would dissuade consumers from purchasing the plaintiff's product. 823 F.3d at 68. But it did not state that extrinsic evidence of materiality was required. Its only reference to extrinsic evidence was in connection with implied falsity, a question that it expressly

distinguished from materiality. Apotex, 823 F.3d at 67–68. While Church & Dwight started with the nature of the statement, it purported ultimately to rely on the district court's finding that "Plaintiff likely suffered a loss of sales by reason of Defendant's false advertising," which was based on the district court's express finding that the plaintiff lost sales because of the false advertising. 843 F.3d at 71. Evidence of lost sales could be considered to be extrinsic evidence, and evidence of the type not presented here by either party. But Church & Dwight's discussion of that evidence tends to support the notion that extrinsic evidence is not strictly required. On appeal, the defendant argued that the plaintiff's lost sales were not due to the false advertising but rather to an important new feature that the defendant was offering. Id. The court assumed that defendant was correct in that argument but nonetheless concluded that the district court's finding that plaintiff "likely" lost market share because of the false advertising was amply supported by the evidence the circuit court had previously discussed (viz the reasonable notion that the misstatement would have been important for a significant number of women) as well as by the fact that the plaintiff and the defendant were direct competitors. Id. at 71 & n.12. In other words, the court ultimately fell back on the nature of the misrepresentation as well as on the fact that the parties were competitors to support the finding that the plaintiff likely lost sales because of the false advertising, which in turn supported a finding that the false advertising was material.

The Court concludes that *Apotex* and *Church & Dwight* establish that, at a minimum, a plaintiff can survive summary judgment and establish materiality when, based on the misstatement on its face and the nature of the product, the court can conclude that the misstatement likely would matter to consumers and influence their purchasing decisions, at least under circumstances where the parties are direct competitors. Not every misstatement about a product necessarily relates to an inherent or material quality of that product such that it is likely

to influence consumer purchasing decisions. The rate of absorption of tizanidine did not on its face relate to an inherent or material quality; as such, some further evidence of materiality was required. Some statements clearly would matter to consumers. At oral argument in this case, the Court posited a statement that a competitor's vitamin pill—if ingested—would cause a certain and extraordinarily painful death for most people. Counsel effectively conceded that no useful purpose would be served by extrinsic evidence in such case; it would simply confirm the obvious. Oral Argument Tr. at 74. Likewise, as in *Church & Dwight*, a misstatement about a product's ability to measure the length of pregnancy duration consistent with the metrics used by the medical profession did tend to support materiality particularly when the evidence showed that the plaintiff and the defendant's products were marketed to women who would wish to know both whether they were pregnant and when they were likely to give birth.

With these principles in mind, the Court turns to the competing claims of the parties.

#### 1. ChromaDex's Claims

Elysium argues that it is entitled to summary judgment on ChromaDex's false advertising claim because ChromaDex does not present evidence to show that the challenged statements were material, and because "[w]ithout evidence of materiality, ChromaDex's false advertising claims fail." Dkt. No. 222 at 19–20. In essence, Elysium's argument is that ChromaDex cannot demonstrate materiality without extrinsic evidence.<sup>27</sup> The Court rejects this argument. As outlined above, when the plaintiff and defendant are direct competitors and the misrepresentation

<sup>&</sup>lt;sup>27</sup> Elysium also argues that ChromaDex's only extrinsic evidence of materiality—the materiality survey conducted by its expert Bruce Isaacson—"was so flawed as to render it unreliable." Dkt. No. 222 at 19. The Court addresses the parties' arguments regarding the reliability of the Isaacson survey in the accompanying Opinion and Order on the parties' *Daubert* motions. Nonetheless, whether the survey is excluded is immaterial to the question whether Elysium is entitled to summary judgment. Even assuming that the Court excludes the survey, it nonetheless rejects Elysium's argument that resulting absence of extrinsic evidence of materiality is fatal to ChromaDex's claims.

is of the nature that would reasonably matter to consumers in deciding which of those companies to purchase from—as in *Church & Dwight*—there is evidence from which a jury could find that the misrepresentation is material. Here, there is no doubt that Elysium and ChromaDex compete directly in the direct-to-consumer NR-containing dietary supplement market; Elysium does not engage with the nature of each of ChromaDex's alleged misrepresentations, nor does it attempt to argue that they are not such misrepresentations that would reasonably matter to consumers in deciding whether to purchase Basis from Elysium or Tru Niagen from ChromaDex. As such, the Court rejects Elysium's argument that absent extrinsic evidence of materiality, ChromaDex cannot demonstrate materiality, and accordingly denies Elysium's motion for summary judgment on ChromaDex's claims as to materiality.

### 2. Elysium's Counterclaims

ChromaDex's motion for summary judgment on Elysium's counterclaims as to materiality relies on the identical argument that the Court rejected in Elysium's motion.

ChromaDex argues that it is entitled to summary judgment because Elysium has not adduced evidence of materiality. Dkt. No. 210 at 28. It notes that Elysium's survey expert, Brian Sowers, testified that he did not test materiality, and was not retained to do so, Dkt. No. 201, Ex. 5 at 22, and it argues that Elysium has not identified any other extrinsic evidence of materiality.

Elysium does not dispute that it has adduced no extrinsic evidence of the impact of ChromaDex's challenged advertising on consumer purchasing decisions. Dkt. No. 250 at 7. It relies on the nature and content of the challenged statements for their materiality asserting that since the statements relate to an inherent quality of Basis they are material by definition. *See*, *e.g.*, Dkt. No. 250 at 12 ("Again, ChromaDex's false statements regarding the evidence of Tru Niagen's effectiveness and superiority to Basis is inherently material."); *id.* at 15 ("Moreover, such deception is material because it relates to an inherent quality of Tru Niagen—its

effectiveness."); *id.* at 17 ("ChromaDex's false advertising that the FDA has confirmed the effectiveness of Tru Niagen also relates to an inherent quality of the product—its efficacy."); *id.* at 18 ("ChromaDex's false advertising that the FDA has confirmed the safety of Tru Niagen three times also relates to an inherent quality of the product—its safety."). In its reply, and at oral argument, ChromaDex reiterates its position that extrinsic evidence of materiality is strictly required, and that it is entitled to summary judgment on that basis. *See* Dkt. No. 262 at 2; Oral Argument Tr. at 4, 8 (arguing that "the courts have been clear that you need extrinsic evidence of materiality" and that "based on the fact that there is no extrinsic evidence of materiality, whether via survey or other evidence that Elysium has presented, . . . summary judgment should be granted in our client's favor as to the counterclaims").

The Court again rejects the argument that extrinsic evidence of materiality is required. Where, as here, the parties are direct competitors, there is no categorical requirement that extrinsic evidence is always required. It will depend on the nature of the alleged misrepresentations and whether it would reasonably influence consumers' decisions as to which company to purchase from. Because the Court rejects ChromaDex's argument, and because ChromaDex does not attempt to analyze the nature of each alleged misrepresentation to argue that it is not such a misrepresentation that would reasonably lead consumers to purchase Elysium's product rather than ChromaDex's product, ChromaDex's motion for summary judgment as to materiality is denied.

Elysium also moves for summary judgment on materiality for the portion of its counterclaims that relate to the Counterfeit Page. Dkt. No. 222 at 25–26. Elysium does not rely on any extrinsic evidence. Rather, it argues that "ChromaDex's claims that Tru Niagen's NR is superior to Basis's NR is a representation regarding the inherent quality of the products," and

that "[t]he false statements on the Counterfeit Page are, therefore, material. *Id.* The alleged misrepresentations on the Counterfeit Page are that the NR in Basis—in contrast to the NR in Tru Niagen—is inauthentic, unsafe, and ineffective. As in *Church & Dwight*, "[i]f consumers, faced with the choice to purchase either [Elysium's] product or the [ChromaDex's], are likely to prefer the [ChromaDex's] product by reason of the [ChromaDex's] false advertising, the falsity of [ChromaDex's] advertising is material to [Elysium's] Lanham Act claim." 843 F.3d at 71. Here, it is entirely reasonable to conclude that the alleged misrepresentations—that while the NR in Tru Niagen is authentic, safe, and effective, the NR in Basis is counterfeit, unsafe, and ineffective—would matter to consumers choosing whether to purchase Tru Niagen or Basis. The evidence is sufficient to create a triable claim as to the materiality of these statements, but it does not entitle Elysium to summary judgment on materiality.

## D. Injury

Both parties move for summary judgment as to the injury element of a Lanham Act false advertising claim. Elysium moves for summary judgment as to ChromaDex's Complaint, arguing that ChromaDex has not adduced evidence as to causation or damages. Dkt. No. 222 at 20. ChromaDex moves for summary judgment as to Elysium's Counterclaim, arguing that Elysium "has no evidence or quantification of harm." Dkt. No. 210 at 1. Elysium also moves for partial summary judgment as to the injury element of the portion of its Counterclaim related to the Counterfeit Page. Dkt. No. 222 at 26. For the reasons that follow, Elysium's motion for summary judgment on injury as to ChromaDex's Complaint is granted; ChromaDex's motion for summary judgment as to Elysium's Counterclaim on injury and damages is granted in part in that, at trial, Elysium will be held to its assertion that it is seeking relief only in the forms of injunctive relief and disgorgement, and not in the form of damages for lost profits; and finally,

Elysium's motion for summary judgment on injury as to the portion of its Counterclaim that relates to the Counterfeit Page is granted.

#### 1. ChromaDex's Claims

Elysium argues that, even if ChromaDex had adduced evidence of a false or misleading statement, it is entitled to summary judgment on ChromaDex's Lanham Act false advertising claim because ChromaDex has not adduced evidence as to causation or damages. Dkt. No. 222 at 20. The only evidence ChromaDex points to as proof of injury is the expert report of its damages expert, Lance Gunderson.

First, in an Opinion and Order addressing the parties *Daubert* motions accompanying this Opinion and Order, the Court has granted Elysium's *Daubert* motion and excluded Gunderson's expert testimony because his report assumed, without any facts or data or evidence, the central propositions upon which the analysis rested—both that without Elysium's allegedly false statements, Elysium would not have made *any* sales of Basis, and that ChromaDex would have made *all* of those sales. It thus is unreliable and fails to satisfy Federal Rule of Evidence 702. In fact, there is uncontradicted evidence that Elysium made sales of Basis prior to any of the allegedly false statements and there is also uncontradicted evidence that Elysium has competitors in the marketplace other than ChromaDex.

Second, even if it were not excluded, Gunderson's report would not be evidence of causation or injury because Gunderson did not seek to demonstrate causation or injury, but rather he simply assumed it. He took the fact of an allegedly false statement and then showed what Elysium's sales were and did the math as to what ChromaDex's sales would have been if each sale that Elysium made had been made by ChromaDex. That is not evidence of causation of injury. It begs the critical question in that analysis, assuming causation rather than

demonstrating it. ChromaDex points to no other evidence that would demonstrate that Elysium's allegedly false statements caused it injury.

Absent any evidence of causation of injury, ChromaDex relies on *Merck Eprova*, in which the Second Circuit held that a presumption of injury would arise in a Lanham Act false advertising case where each of two conditions was satisfied (1) the "plaintiff has met its burden of proving deliberate deception"; and (2) the relevant market is a two-player market. 760 F.3d at 260–61. Some discussion of the case is required to address ChromaDex's argument.

In Merck Eprova, the Second Circuit recognized that in the ordinary false advertising case involving non-comparative advertising, no presumption of injury arises and the plaintiff must provide "some indication of actual injury and causation" because the injury "accrues equally to all competitors; none is more likely to suffer from the offending broadcasts than any other." Id. at 259 (internal quotation marks omitted) (quoting McNeilab, 848 F.2d at 38). The court reiterated the concerns it had previously expressed in McNeilab and that the Eighth Circuit echoed in *Porous Media* about speculative injury: "Where a defendant is guilty of misrepresenting its own product without targeting any other specific product, it is erroneous to apply a rebuttable presumption of harm in favor of a competitor. Otherwise, a plaintiff might enjoy a windfall from a speculative award of damages by simply being a competitor in the same market." Id. at 260 (internal quotation marks and alteration omitted) (quoting Porous Media Corp. v. Pall Corp., 110 F.3d 1329, 1334 (8th Cir. 1997)). The court reiterated that it had previously found that a presumption of injury would arise only in two specific circumstances: (1) where the defendant made a false comparative advertising claim, see McNeilab, 848 F.2d at 38, and (2) where the statement at issue was derogatory and undoubtedly referred only to the plaintiff, see Time Warner Cable, 497 F.3d at 162. In the former circumstance, "[a] misleading

comparison to a *specific competing product* necessarily diminishes that product's value in the minds of the consumer." *Id.* at 259 (internal quotation marks omitted) (quoting *McNeilab*, 848 F.2d at 38). In the latter circumstance, a presumption could arise that the plaintiff was injured because, even though the commercial did not identify the plaintiff by name, consumers would "undoubtedly understand" the derogatory comments it made about a competitor to refer only to plaintiff, *id.* (quoting *Time Warner Cable*, 497 F.3d at 162). In short, the presumption would apply either where the advertisements explicitly directed consumers to abandon the competitor in favor of the advertiser or where they implicitly did so because the disparaging comparative comments would be understood necessarily to refer to the competitor.

The *Merck Eprova* court held that the same logic supported the recognition of a presumption in a "two-player market" where there is evidence of "deliberate deception." In such a market, where there are only two companies—the plaintiff and the defendant—who are "obviously in direct competition," it would follow that the party who had not engaged in false advertising would be injured by the false advertising of the other and thus there would be "no risk of speculative injury." *Id.* at 260–61; *see also Dependable Sales & Serv., Inc. v. TrueCar, Inc.*, 394 F. Supp. 3d at 374.

ChromaDex, however, has not identified evidence to support either of the two conditions necessary for the *Merck Eprova* presumption to apply. First, the record is devoid of any evidence that, if Elysium's statements were deceptive, such deception was deliberate.

ChromaDex argues—in context of its argument that it is entitled to disgorgement of Elysium's profits—that "[t]he undisputed record shows that Elysium repeatedly disregarded its scientific advisory board, its employees, and even its own customers in continuing to advertise Basis based on outright falsehoods, purposefully misleading messages, and stolen pedigree." Dkt. No. 255 at

26. But ChromaDex points to no evidence to support its assertion that Elysium's messages were "purposefully misleading." "[C]onclusory statements, conjecture, or speculation by the party resisting the motion will not defeat summary judgment." *Kulak v. City of New York*, 88 F.3d 63, 71 (2d Cir. 1996).

Second, although it is undisputed that Elysium and ChromaDex are direct competitors in the market for sale of supplements to consumers, the evidence demonstrates that they are not the only competitors in a two-player market. Indeed, ChromaDex concedes that there were other NR-containing dietary supplements that competed with Basis and Tru Niagen during the relevant time period, including Life Extension, Thorne, and others. *See* Dkt. No. 209, Ex. A, Schedule 9.1.<sup>28</sup>

ChromaDex argues that the Court should deem it and Elysium to be the only two competitors in the market for the sale of NR-based supplements to consumers because "[t]he only other companies that sold NR-containing supplements in the U.S. during the relevant period sold ChromaDex's NIAGEN wholesale ingredient." Dkt. No. 232 at 2. There is some dispute whether that is true. Elysium points to evidence to the contrary, *see* Dkt. No. 273 at 5, and at argument even ChromaDex admitted that some NR that others use may come from abroad, *see* 

<sup>&</sup>lt;sup>28</sup> The parties dispute how to define the relevant market with which they each compete. ChromaDex would define it narrowly, as "companies that sell NR-containing dietary supplements." Dkt. No. 232 at 2. Elysium would define it more broadly; it asserts that it "competes with many products other than NR supplements," Dkt. No. 273 at 5, and cites the testimony of Dan Alminana, its 30(b)(6) witness on Basis's competitors, *see* Dkt. No. 257, Ex. 9 at 15, that "its competitors include any supplements that contain NAD+ precursors—such as NR, NMN and other combination products—along with resveratrol supplements and other products that target sirtuins, as well as products that purport to create a particular effect in the user, most often products that purport to boost energy, support metabolic and cellular health, and increase metabolism," Dkt. No. 273 at 5 (citing Dkt. No. 257, Ex. 9 at 113–16). Because the Court finds that ChromaDex's argument fails even under its narrower market definition, it assumes but does not decide that the narrower definition applies.

Oral Argument Tr. at 80–81 (stating that ChromaDex "was the only supplier *in the U.S. marketplace* of NR" (emphasis added)), but construing the evidence in favor of ChromaDex, the Court is prepared assume that a jury could find that every other competitor to Elysium used NR purchased from ChromaDex.

Even assuming the truth of ChromaDex's claim, however, it would not convert the direct-to-consumer dietary supplement market into a two-player market such that a presumption of injury arises. On ChromaDex's theory, it could bring and win a Lanham Act case even if Elysium's advertising did not cause any customer to purchase a product from Elysium rather than from ChromaDex and even if Elysium's advertising caused no injury to ChromaDex's reputation on the sole basis that the sales lost by another of Elysium's competitors to whom ChromaDex sold its NR also presumptively caused injury to ChromaDex.

The Supreme Court considered a related issue in *Lexmark Intern. v. Static Control*, 572 U.S. 118, 128 (2014). A retailer who could prove that Elysium's advertising injured its reputation or diverted sales from it to Elysium would have a cause of action under the Lanham Act and could recover damages for its injury. It would be able to show proximate causation. Section 43(a) of the Lanham Act incorporates a proximate causation requirement, meaning that the "statutory cause of action is limited to plaintiffs whose injuries are proximately caused by violations of the statute." *Id.* at 132. "Put differently, the proximate-cause requirement generally bars suits for alleged harm that is 'too remote' from the defendant's unlawful conduct. That is ordinarily the case if the harm is purely derivative of 'misfortunes visited upon a third person by the defendant's acts." *Id.* at 133 (quoting *Holmes v. Sec. Investor Protection Corp.*, 503 U.S. 258, 268–69 (1992)). The *Lexmark* Court thus held that:

a plaintiff suing under § 1125(a) ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising;

and that that occurs when deception of consumers causes them to withhold trade from the plaintiff. That showing is generally not made when the deception produces injuries to a fellow commercial actor that in turn affect the plaintiff. For example, while a competitor who is forced out of business by a defendant's false advertising generally will be able to sue for its losses, the same is not true of the competitor's landlord, its electric company, and other commercial parties who suffer merely as a result of the competitor's "inability to meet [its] financial obligations."

*Id.* at 133–34 (quoting *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 458 (2006)).

It follows that even assuming ChromaDex is the sole supplier to all of several customers who themselves may have suffered injury as a result of Elysium's advertising that fact would not create an inference that ChromaDex itself suffered cognizable injury. The only persons to have suffered injury may have been ChromaDex's retail customers who were competing with Elysium. ChromaDex might be able to establish injury but it would have to prove it; it could not ask the jury to presume it.<sup>29</sup>

Accordingly, a presumption of injury against it and absent anything in the record to support "some indication of actual injury and causation" from its allegedly false advertising, *Merck Eprova*, 760 F.3d at 259, Elysium is entitled to summary judgment on ChromaDex's false advertising claims against it.

ChromaDex additionally argues that it is entitled to disgorgement of Elysium's profits as an alternative measure of damages. However, ChromaDex's inability to demonstrate actual

<sup>&</sup>lt;sup>29</sup> A plaintiff need not be a direct competitor to establish injury and to bring a Lanham Act action. In *Lexmark* itself, the Court held that a company which was not a direct competitor had suffered injury caused by the defendant's conduct within the meaning of the Lanham Act both because the defendant had disparaged its business and because it alleged that the products it designed, manufactured, and sold were necessary for and had no other use than in the product or service (refurbishing Lexmark toner cartridges) that defendant disparaged. *Id.* at 139. But to establish injury under either theory, ChromaDex would have to offer proof. It has not done so here. Indeed, the *Lexmark* Court emphasized that "[a]lthough we conclude that [the plaintiff] has *alleged* an adequate basis to proceed under § 1125(a), it cannot obtain relief without *evidence* of injury proximately caused by Lexmark's alleged misrepresentations. We hold only that Static Control is entitled to a chance to prove its case." *Id.* at 140.

injury and causation is not merely a flaw in its damages calculation, but it is also a flaw inherent in its Lanham Act claim which precludes a finding of Lanham Act liability and thus any measurement of damages. *See Dependable Sales*, 394 F. Supp. 3d at 372 ("[P]laintiffs' failure to come forward with evidence of injury precludes their disgorgement claim."). ChromaDex's claim for injunctive relief similarly fails. Even under the lower standard applied when the plaintiff seeks injunctive relief—"whether it is likely that [the defendant's] advertising has caused or will cause a loss of [the plaintiff's] sales, not whether [plaintiff] has come forward with specific evidence that [the defendant's] ads actually resulted in some definite loss of sales"—it is still true that "the likelihood of injury and causation will not be presumed, but must be demonstrated." *Johnson & Johnson*, 631 F.2d at 190. There is no triable issue as to whether ChromaDex has demonstrated a likelihood of injury and causation, because the record is devoid of any evidence that would support such a finding.

## 2. Elysium's Counterclaims

ChromaDex argues that it is entitled to summary judgment on Elysium's Lanham Act false advertising claims because although the Counterclaim includes a request for monetary damages, Elysium has not offered any theory or quantification of damages. Dkt. No. 210 at 29. Elysium responds that it is not seeking damages, but rather is seeking injunctive relief and disgorgement. Dkt. No. 250 at 23.<sup>30</sup> ChromaDex's motion for summary judgment is granted in

<sup>&</sup>lt;sup>30</sup> Elysium's memorandum appears to suggest that an award of disgorgement could be warranted even absent a showing of injury and causation. *See* Dkt. No. 250 at 23 (citing *Dependable Sales & Serv., Inc. v. TrueCar, Inc.*, 377 F. Supp. 3d 337, 342 (S.D.N.Y. 2019), *on reconsideration*, 394 F. Supp. 3d 368 (S.D.N.Y. 2019), as stating that "[u]nder the law of the Second Circuit, even where a plaintiff has not demonstrated injury, the equitable disgorgement of a defendant's profits may be ordered in the interests of deterrence if the plaintiff can show that defendant willfully violated the Lanham Act"). However, on reconsideration in *Dependable Sales*, the court held that "plaintiffs' failure to come forward with evidence of injury precludes their disgorgement claim." 394 F. Supp. 3d at 372.

that at trial Elysium will be held to its representation that it is not seeking relief in the form of damages.<sup>31</sup> To be entitled to any form of relief, Elysium will have to demonstrate injury and causation; however, since ChromaDex makes no arguments regarding Elysium's ability or inability to do so on this motion, and instead focuses on quantification of damages, the Court does not consider whether the evidence in the record is sufficient to create a triable issue as to causation and injury on Elysium's Counterclaim.

Elysium also moves for partial summary judgment on liability on the portion of its

Counterclaim that relates to the Counterfeit Page. Because this page refers to Basis by name
and—even in prior versions that did not include explicit mention of Basis—includes a picture of
Basis's bottle, thus clearly referring to Basis, Elysium is entitled to rely on the presumption of
injury recognized in *McNeilab* and *Time Warner Cable*. A presumption of injury arises where
the false or misleading advertising makes reference "to a specific competing product," which
"necessarily diminishes that product's value in the minds of the consumer," *McNeilab*, 848 F.2d
at 38, and where "even though [the challenged advertising] does not identify [the competitor] by
name, consumers . . . undoubtedly understand [the] derogatory statement . . . as referring to [the

<sup>&</sup>lt;sup>31</sup> In its reply brief, ChromaDex briefly argued that Elysium has not "presented any evidence or opinion . . . on causation." Dkt. No. 262 at 14. It further argued that to obtain an injunction, Elysium must first "establish that there is no adequate remedy at law," and that because Elysium "has not even attempted to quantify that remedy," it cannot obtain relief in the form of an injunction. *Id.* At oral argument, ChromaDex extended this reasoning to disgorgement, arguing that disgorgement is only available under the Lanham Act where damages would be insufficient to compensate the plaintiff, and that as such, because Elysium does not seek damages, they cannot get disgorgement. None of these arguments appear in ChromaDex's initial briefing of its motion for summary judgment; as such, the Court does not consider them here. *See American Hotel Intern. Group, Inc. v. OneBeacon Ins. Co.*, 611 F. Supp. 2d 373, 375 (S.D.N.Y. 2009); ("[A] district court is free to disregard argument raised for the first time in reply papers, especially on a motion for summary judgment."); *Playboy Enters., Inc. v. Dumas*, 960 F. Supp. 710, 720 n.7 (S.D.N.Y. 1997) ("Arguments made for the first time in a reply brief need not be considered by a court.").

competitor]," *Time Warner Cable*, 497 F.3d at 162. Because the Counterfeit Page fits squarely into this category of advertising, a presumption of injury applies, and Elysium is entitled to summary judgment as to the injury element of its Lanham Act claim.

#### II. The Parties' Remaining Federal and State Law Claims

The same conclusions as reached in the Lanham Act context apply to the parties' remaining federal claims of unfair competition under the Lanham Act and state law claims under New York General Business Law § 349.

## A. Unfair Competition Under the Lanham Act

Both parties assert claims for unfair competition under the Lanham Act in addition to their false advertising Lanham Act claims; however, both parties agree this claim rises or falls with their false advertising claim. *See* Dkt. No. 210 at 30; Dkt. No. 222 at 10. "[T]here is no specific Federal cause of action for unfair competition. Instead unfair competition under the Lanham Act is a category of claims consisting primarily of causes of action for false designation of origin and false advertising." *Pot Luck, L.L.C. v. Freeman*, 2009 WL 693611, at \*4 (S.D.N.Y. Mar. 10, 2009); *see also Sussman-Automatic Corp. v. Spa World Corp.*, 15 F. Supp. 3d 258, 273 (E.D.N.Y. 2014) ("For this reason, the Court dismisses the Plaintiff's unfair competition claim under the Lanham Act as duplicative of the Plaintiff's trademark infringement and false advertising claims under that statute."); *C=Holdings B.V. v. Asirim Corp.*, 992 F. Supp. 2d 223, 242 (analyzing "false advertising and unfair competition under Section 43(a)(1)(B) of the Lanham Act" jointly).

#### B. New York General Business Law § 349

New York General Business Law Section 349 prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service." "The standards for bringing a NYGBL § 349 claim 'are substantially the same as those applied to

claims brought under' § 43(a) of the Lanham Act." Davis v. Avvo, Inc., 345 F. Supp. 3d 534,

540 (S.D.N.Y. 2018) (quoting Avon Prods., Inc. v. S.C. Johnson & Son, Inc., 984 F. Supp. 768,

800 (S.D.N.Y. 1997)); see also Johnson & Johnson-Merck Consumer Pharm. Co. v. Smithkline

Beecham Corp., 1991 WL 206312, at \*9 (S.D.N.Y. Oct. 1, 1991), aff'd, 960 F.2d 294 (2d Cir.

1992) ("The legal test for liability under §§ 349 and 350 of the New York General Business Law

is the same as the test for violation of § 43(a) of the Lanham Act." (citing *Proctor & Gamble Co.* 

v. Chesebrough-Pond's, Inc., 588 F. Supp. 1082, 1083 n.4 (S.D.N.Y.), aff'd, 747 F.2d 114 (2d

Cir. 1984); then citing Bi-Rite Enterprises, Inc. v. Button Master, 555 F. Supp. 1188, 1192–93

(S.D.N.Y. 1983))).

**CONCLUSION** 

The motions for summary judgment are each GRANTED IN PART and DENIED IN

PART. Because the Court has granted summary judgment for Elysium on the injury element of

ChromaDex's Lanham Act false advertising claim, ChromaDex's Complaint is dismissed in full.

Elysium's Counterclaim survives in part; all counterclaims as to statements as to which the Court

has granted ChromaDex's motion for summary judgment on the falsity element of Elysium's

Lanham Act false advertising claim are dismissed.

SO ORDERED.

Dated: February 3, 2022

New York, New York

LEWIS J. LIMAN

United States District Judge

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